

LSF Research
Prepared by
HealthValue
Consulting (Pty) Ltd
and IQVIA

October 2026

Localising MedTech Manufacturing in South Africa



ABOUT THIS STUDY

This final report presents the consolidated findings, analysis, and recommendations of the South African Medical Technologies Demand Mapping Study commissioned by the Localisation Support Fund. Grounded in the strategic objectives of the Medical Technology Masterplan, the report synthesises evidence from desk research, available market data, extensive stakeholder engagements, and analytical modelling. The findings provide an evidence-based foundation for targeted localisation strategies and interventions aimed at strengthening domestic MedTech manufacturing capabilities and supporting the implementation of the Medical Technology Masterplan. This report serves as a comprehensive reference for policymakers, industry stakeholders, and investors to guide localisation-focused decision-making and implementation.

ABOUT LSF

The Localisation Support Fund NPC (“LSF”) was established as a non-profit company in 2021, funded by private sector contributors committed to localising manufacturing in South Africa. The LSF is a network orchestrator within the localisation ecosystem facilitating the connection between supply and demand participants, enhancing the value of the interactions by funding industry research and the deployment of technical expert resources to accelerate or unblock opportunities for localisation and growth in the manufacturing sector.

ABOUT SERVICE PROVIDER

HealthValue Consulting (Pty) Ltd. (HVC) is a strategic advisory consultancy dedicated to the healthcare sector. HVC offers a variety of services designed to enhance and optimise different facets of the healthcare sector such as local manufacturing, trade, strategic planning, policy development and analysis, as well as regulatory and health systems strengthening. Our expertise covers multiple domains within healthcare, enabling us to deliver comprehensive solutions to our clients, which include private sector, trade associations, think tanks, consultancies, and development organisations. HVC is based in Johannesburg, South Africa. HVC’s engagement with international and local clients has included projects across the African continent, including South Africa, Ghana, Mozambique, Nigeria, Tanzania, Uganda, Burkina Faso, Rwanda, Ethiopia, and Botswana. This extensive experience across multiple African nations highlights capabilities across the continent.

IQVIA is a global leader in healthcare and public health consulting, leveraging data, technology, advanced analytics, and human expertise to advance healthcare, across the globe. With 70+ years of experience, IQVIA operates in 100+ countries across 6 continents. IQVIA serves key healthcare organisations and decision makers around the world like government agencies, donors and multilateral agencies, development banks, life science and pharmaceutical clients, and healthcare providers across the globe.

DISCLAIMER

This report has been prepared in fulfilment of the study to map the landscape for medical technologies in South Africa and to assess the potential for local sourcing and manufacturing. It presents the final findings, analysis, and conclusions of the study, drawing on desk research, stakeholder engagements, and quantitative and qualitative analysis undertaken over the course of the project. While every effort has been made to ensure comprehensive and balanced representation of stakeholder perspectives, the findings are based on the available market data, desk research, and inputs received during the study period and should be interpreted within this context. No omissions are intentional or intended to exclude or prejudice any stakeholder or interest group.

LSF or any of their respective affiliates, representatives, partners, directors, officers, employees, advisers or agents ("Representatives") do not accept any liability or responsibility for the accuracy or completeness of or make any representation or warranty or give any undertaking, express, implied or tacit, with respect to the information and any opinions contained in this report or information on which this report is based or with respect to any other information or opinion made available or to be made available, whether in written or oral or other format, to any recipient. The recipient will be liable for forming their own views as to the accuracy and completeness of the information.

To the fullest extent permitted by law, in no circumstances will the LSF and/or Representatives be responsible or liable for any direct, indirect or consequential loss or loss of profit arising from the use of this report, its contents, its omissions, reliance on the information contained within it or on opinions communicated in relation thereto or otherwise arising in connection therewith.

The report has not been independently verified by LSF and/or its Representatives. LSF and/or its Representatives do not undertake or expect to update or otherwise revise this report and expressly disclaim any obligation to disseminate any updates or revisions, including to any financial data or forward-looking statements, that may result from any change in expectations, conditions or any other events or circumstances arising after the date of this report.

The information includes forward-looking statements which include, without limitation, any statements preceded by, followed by or including words such as "target", "objective", "believe", "expect", "aim", "intend", "may", "anticipate", "estimate", "plan", "project", "will", "can have", "likely", "should", "would", "could" and other words and terms of similar meaning or the negative thereof.

The forward-looking statements in the report are based on beliefs and projections and on information currently available to them; however, these forward-looking statements are subject to risks, uncertainties and assumptions. Should risks or uncertainties materialise, or should any underlying assumptions prove to be incorrect, the actual financial conditions or results of operations could differ materially from those described herein as anticipated, believed, estimated or expected. No representation or warranty is made that any forward-looking statement will come to pass. No one undertakes to update or revise any such forward-looking statement.

DISCLOSURE

This research was commissioned by the LSF and was conducted independently by HealthValue Consulting. The lead consultant responsible for this report as well as the overall project was HealthValue Consulting. The opinions or recommendations contained in this report represent the views of the authors and do not necessarily reflect the views and opinions of the LSF. This report is addressed to the LSF solely for its use and benefit for purposes of the demand mapping study, and may not be transmitted to any other person, nor quoted or referred to in any public document, nor filed with any governmental agency or person without the LSF's prior written consent. Unless otherwise agreed to by the LSF in writing, no person, other than the LSF, is entitled to rely on this Report and LSF shall have no responsibility or liability to any party who has access to this report, whether in contract, delict (including gross negligence) or otherwise.

ACKNOWLEDGEMENT

The authors would like to express their sincere appreciation to the **Localisation Support Fund (LSF)** for commissioning and supporting this study. We are particularly grateful to the Steering Committee members, **Fundile Gebremedhin**, Director: Medical Devices & HealthTech Procurement Management, Department of Health; **Swasthi Soomaroo**, Director: Pharmaceuticals and Medical Devices, Department of Trade, Industry and Competition (DTIC); and **Victor van Vuuren**, Director, Holavic Consulting, for their guidance, strategic direction, and valuable contributions throughout the project.

We also extend our sincere thanks to representatives from government, public and private healthcare institutions, industry associations, manufacturers, distributors, healthcare providers, and other stakeholders who generously contributed their time, expertise, data, and insights during consultations and interviews. Their participation and collaboration were instrumental in informing the analysis and strengthening the evidence base for this study.

COPYRIGHT

© 2026. All rights reserved. This document is copyrighted to the LSF. Prior written permission must be obtained.

Contents

Table of Figures	6
List of Tables	7
Abbreviations	8
Executive Summary	10
Section 1: Context and Rationale	15
Section 2: Market Structure and Trade Analysis	33
Section 3: Demand Estimation.....	38
Section 4: Implications for Localisation	53
Section 5: Way Forward.....	85
Annexures	89
Reference List	137



Table of Figures

FIGURE 1: THE SOUTH AFRICAN MEDTECH PARADOX	16
FIGURE 2: CONSEQUENCES OF IMPORT DEPENDENCE	16
FIGURE 3: MARKET AND DRIVERS.....	17
FIGURE 4: BARRIERS TO LOCALISATION	17
FIGURE 5: POLICY MOMENTUM: FROM UNTAPPED POTENTIAL TO COORDINATED RESPONSE	18
FIGURE 6: A SELECTIVE, EVIDENCE-BASED PATH TO LOCALISATION (SAMRC 2022-23).....	18
FIGURE 7: FOUR QUESTIONS THAT DRIVE PRIORITISATION	19
FIGURE 8: WHAT THE STUDY SETS OUT TO ACHIEVE	20
FIGURE 9: REPRESENTATION OF STAKEHOLDER GROUPS IN CONSULTATIONS.....	25
FIGURE 10: SUPPLIER SURVEY RESPONDENTS' PROFILE (MULTIPLE CHOICE)	26
FIGURE 11: EVIDENCE SYNTHESIS AND DATA TRIANGULATION	29
FIGURE 12: OVERVIEW OF MEDTECH MARKET SIZE AND GROWTH	34
FIGURE 13: IMPORT-DEPENDENT MARKET	35
FIGURE 14: PRODUCT LEVEL ANALYSIS OF IMPORT VALUE AND COUNTRIES OF IMPORT	37
FIGURE 15: GEOGRAPHIC SPREAD OF PROCUREMENT SPEND.....	39
FIGURE 16: PROCUREMENT SHARE OF DEVICES (IN %)	40
FIGURE 17: PROPORTION OF PROCUREMENT OF DEVICES IN THREE PROVINCES.....	41
FIGURE 18: VALUE OF PROCUREMENT AT PROVINCIAL LEVEL	41
FIGURE 19: CUMULATIVE SPEND ON EACH DEVICE CATEGORY	43
FIGURE 20: NHLS REVENUE IN R MN (SOURCE: NHLS ANNUAL REPORTS)	49
FIGURE 21: TOTAL TEST VOLUME BY PROVINCES IN MILLION (SOURCE: NHLS ANNUAL REPORTS).....	49
FIGURE 22: NHLS TOP 10 TESTS BY VOLUME, 2022/23 – 2024/25.....	50
FIGURE 23: KEY PROVINCES WHERE LOCALISATION CLUSTERED.....	54
FIGURE 24: REPORTED PRODUCT CATEGORIES.....	56
FIGURE 25: CUSTOMER MIX.....	57
FIGURE 26: OVERALL LOCAL MANUFACTURED V/S IMPORT SPLIT	57
FIGURE 27: LOCAL MANUFACTURE VS IMPORT SPLIT BY CATEGORY FOR PUBLIC AND PRIVATE USERS.....	58
FIGURE 28: SUPPLY SPLIT: DOMESTIC V/S EXPORTED	59
FIGURE 29: CAPACITY UTILISATION OF LOCAL MANUFACTURERS	59
FIGURE 30: BARRIERS FOR FULL LOCAL MANUFACTURING	61
FIGURE 31: BARRIER FOR FULL LOCAL MANUFACTURING: CATEGORY WISE	62
FIGURE 32: CHALLENGES IN SERVING PUBLIC SECTOR	63
FIGURE 33: ENABLERS FOR LOCAL MANUFACTURING	66
FIGURE 34: KEY ENABLERS FOR LOCALISATION	69
FIGURE 35: LOCALISATION PATHWAY	72
FIGURE 36: APPETITE FOR MOVING UP IN VALUE CHAIN.....	72
FIGURE 37: POTENTIAL DEVICES FOR LOCALISATION	73
FIGURE 38: POLICY AND MARKET RECOMMENDATIONS	79
FIGURE 39: IMPLEMENTATION CONSIDERATIONS	86

List of Tables

TABLE 1: TRADE DATA SOURCES	22
TABLE 2: DATA SOURCES FOR ANALYSIS OF PROCUREMENT	23
TABLE 3: KEY THEMES FOR LOCALISATION ANALYSIS.....	28
TABLE 4: KEY BARRIERS TO LOCALISATION	63
TABLE 5: CHARACTERISTICS OF RESPONSIVE MANUFACTURING EPISODES	66
TABLE 6: PROCUREMENT DESIGN FEATURES SUPPORTING LOCAL PARTICIPATION	67
TABLE 7: CHARACTERISTICS AND BENEFITS OF HYBRID SUPPLY MODELS	67
TABLE 8: CHARACTERISTICS OF EXPORT COMPETITIVE LOCAL NICHES.....	68
TABLE 9: COLLABORATIVE ENABLERS ADDRESSING SYSTEMIC CONSTRAINTS	68

Abbreviations

Acronym	Expansion
AfCFTA	African Continental Free Trade Area
BAS	Basic Accounting System
B-BBEE	Broad-Based Black Economic Empowerment
BNP	B-type Natriuretic Peptide
CAGR	Compound Annual Growth Rate
CBC	Complete Blood Count
CMS	Council for Medical Schemes
CSIR	Council for Scientific and Industrial Research
CT	Computed Tomography
DTIC	Department of Trade, Industry and Competition
FT3	Free Triiodothyronine
FT4	Free Thyroxine
FX	Foreign Exchange
GHTF	Global Harmonization Task Force
HHI	Herfindahl-Hirschman Index
HIV	Human Immunodeficiency Virus
HS	Harmonized System
ICU	Intensive Care Unit
IDC	Industrial Development Corporation
IPC	Infection Prevention and Control
IVD	In Vitro Diagnostic
KIIs	Key Informant Interviews
LOGIS	Logistical Information System
LSF	Localisation Support Fund
MDMSA	Medical Device Manufacturers of South Africa
MedTech	Medical Technology
MIIN	Management Information Item Number
MRI	Magnetic Resonance Imaging
NHLS	National Health Laboratory Service
NPC	Non-Profit Company
NPWT	Negative Pressure Wound Therapy
OEM	Original Equipment Manufacturer
PCT	Procalcitonin
PET	Positron Emission Tomography
POCT	Point-of-Care Testing
PPE	Personal Protective Equipment

proBNP	N-terminal Pro B-type Natriuretic Peptide
PSA	Prostate-Specific Antigen
QMS	Quality Management System
RDT	Rapid Diagnostic Test
SAACP	South African Association of Community Pharmacists
SAHPRA	South African Health Products Regulatory Authority
SALDA	Southern African Laboratory Diagnostics Association
SAMED	South African Medical Technology Industry Association
SAMRC	South African Medical Research Council
SADC	Southern African Development Community
SARS	South African Revenue Service
SME	Small and Medium Enterprise
Stats SA	Statistics South Africa
TIPS	Trade and Industrial Policy Strategies
TSH	Thyroid Stimulating Hormone
WCMDC	Western Cape Medical Devices Cluster
WHO	World Health Organization

Executive Summary

1. PURPOSE AND CONTEXT

The MedTech Demand Mapping Study was commissioned to provide an evidence-based assessment of market demand, procurement patterns, local manufacturing capability and localisation opportunities across South Africa's medical technology sector. South Africa is the largest medical technology (MedTech) market on the African continent, yet remains heavily dependent on imported medical technologies. While demand for medical devices continues to expand, driven by population growth, increasing healthcare utilisation, disease burden and investment in healthcare infrastructure, local manufacturing participation remains limited to selected product categories and value-chain segments.

The study was undertaken to address a critical information gap facing policymakers, industry and investors. Although localisation has become a strategic priority under the Medical Technology Masterplan, limited evidence has existed regarding which products are procured by the health system, where local manufacturing capability already exists, which categories present realistic localisation opportunities, and what barriers prevent greater local participation. The study therefore sought to move beyond broad discussions of import dependence and develop a robust, actionable localisation agenda grounded in real procurement demand, supplier capability and market conditions.

Ultimately, the study aims to support healthcare resilience, strengthen industrial development, improve supply security, create employment opportunities and position South Africa as a regional MedTech manufacturing hub by identifying practical and commercially feasible localisation pathways.

2. METHODOLOGY

The study applied a mixed-methods, three-stage framework. This approach was essential given the fragmented nature of the MedTech industry, the uneven availability of data, and the need to balance quantitative signals with the operational realities facing firms on the ground.

The first stage focused on trade and procurement analysis. Trade data from SARS, and Statistics South Africa's Supply and Use Tables were analysed to understand import dependence, product categories, and source markets. This analysis was complemented by public procurement datasets including National Treasury BAS expenditure data, LOGIS procurement records, National Treasury transversal

contracts, National Health Laboratory Service (NHLS) annual reports and Council for Medical Schemes (CMS) industry reports and healthcare utilisation annexures. Together, these datasets provided visibility into what products the healthcare system procures, from whom they are purchased, and where opportunities for localisation may exist.

The second stage involved extensive stakeholder engagement. Key informant interviews were conducted across government departments, regulators, healthcare providers, industry associations, academic institutions and manufacturers. Broader virtual sessions were hosted with companies with the support of the relevant industry associations to share key elements of the research methodology and to gain further insights into the available datasets for the sector. In parallel, a supplier survey was conducted representing manufacturers, distributors, importers and assemblers. The survey was used to validate local manufacturing capability, identify localisation barriers, assess industry readiness and understand future expansion intentions.

The final stage focused on evidence synthesis and prioritisation. Findings from the trade analysis, procurement data, transversal contracts, supplier survey responses and stakeholder consultations were systematically triangulated to identify categories where demand, manufacturing capability, regulatory feasibility and industry willingness to invest converge. This process ensured that prioritised opportunities reflected not only market demand but also realistic industrial development potential.

3. MARKET STRUCTURE, DEMAND AND IMPORT DEPENDENCE

The analysis confirms that South Africa's MedTech market remains structurally import dependent despite growing healthcare demand. Between 2021 and 2022, total medical appliance¹ supply increased from R57.2 billion to R67.5 billion, while imports increased from R44.7 billion to R54.6 billion. As a result, the import share of total supply increased from 78.1% to 80.8%, indicating that rising demand is being met primarily through foreign producers rather than local manufacturing.

Between 2021 and 2025, South Africa imported approximately R155 billion worth of medical technologies. Surgical and medical instruments represented the largest import category, while advanced medical technologies, diagnostic equipment and implantable devices remained heavily dependent on imports from the United States, Germany and other developed manufacturing markets. China dominated many lower-complexity product categories including consumables, rehabilitation products, syringes and dressings. Several categories also displayed high supplier concentration, creating potential supply-chain risks.

¹ *SUT "medical appliances" (CPC 481-484) also includes precision, optical and photographic instruments and watches and clocks

Public-sector demand remains substantial and growing. BAS data indicates approximately R50.3 billion in public-sector MedTech procurement between 2021 and 2025, concentrated primarily in Gauteng, Western Cape and KwaZulu-Natal. Imaging equipment, medical equipment, surgical products, dressings and implantable devices accounted for a significant share of expenditure.

LOGIS data provides visibility into actual purchasing behaviour across the public healthcare system. The data demonstrates that procurement demand is substantial and growing rapidly across multiple categories. Importantly, growth is not concentrated solely within technologically complex products. Categories such as assistive and rehabilitation products, dressings, respiratory accessories, infection prevention and control (IPC) products, medical furniture, surgical consumables, administration sets, consumables and accessories all show sustained procurement demand, creating a platform for localisation where manufacturing capability already exists.

IVD demand remains highly dependent on imported technologies. Reagents account for most of the expenditure in the country and procurement is concentrated among multinationals such as Abbott, Cepheid, Roche, Siemens, Becton, Dickinson and Company, Beckman Coulter, bioMérieux and others.

Stakeholder consultations consistently highlighted procurement uncertainty, delayed payments, fragmented purchasing practices and the absence of long-term volume commitments as key barriers to expansion.² Manufacturers generally did not argue for market protection alone; rather, they emphasised the need for a more predictable operating environment that would justify investment in equipment, product development, quality systems and workforce expansion.

4. LOCAL MANUFACTURING CAPABILITY AND LOCALISATION OPPORTUNITIES

THE CENTRAL PARADOX

South Africa is the largest MedTech market on the continent and public procurement continues to grow, yet local manufacturing has not expanded with it. Demand growth is being absorbed by imports.

The constraint is not market demand. It is the inability of the industrial ecosystem to convert demand into local manufacturing.

² These findings align with the representations made by the industry in parliament during the sessions titled, 'Colloquium on South Africa's Industrial Development Strategy (Day 2) with Deputy Minister', available at: https://pmg.org.za/committee-meeting/43448/?utm_campaign=minute-alert&utm_medium=email&utm_source=transactional

01 CAPABILITY IS STRONGER THAN ASSUMED

Procurement analysis, the supplier survey and stakeholder consultations each identified established manufacturing across multiple device categories. Local capability already exists in significant parts of the value chain.

IMPLICATION Scale, upgrade and sustain what exists rather than build new industries from zero.

02 CAPACITY IS AVAILABLE, CERTAINTY IS NOT

Manufacturers reported spare production capacity and willingness to expand. Fragmented procurement, short contracting cycles, weak demand visibility and delayed payment were named repeatedly as the binding constraints.

IMPLICATION Demand certainty will move localisation further than mandates. Multi-year volume commitment is the primary instrument.

03 PROCUREMENT IS THE INDUSTRIAL LEVER

Uncertainty over future volumes makes it difficult to justify investment in tooling, equipment, workforce and product development. Stakeholders and suppliers agreed on this point independently.

IMPLICATION Treat the procurement system as industrial policy, not only as a purchasing function.

04 THE ISSUE IS COST AND REGULATIONS

Certification cost, thin local testing infrastructure and long approval timelines fall disproportionately on smaller firms.

IMPLICATION Improve predictability and expand testing and validation access.

05 INDUSTRY APPETITE ALREADY EXISTS

Most localisation opportunities identified through procurement analysis aligned with the expansion plans firms had already formed. Industry and policy priorities are substantially convergent.

IMPLICATION The task is enabling execution of investments firms already judge commercially viable, not persuasion.

06 UPGRADE THE IMPORTERS

Many firms in the supply chain operate as distributors, importers or assemblers, yet already hold regulatory registration, customer relationships, procurement experience and market access.

IMPLICATION Moving existing suppliers up the value chain may yield more capacity, faster, than attracting new entrants.

07 ONE STRATEGY WILL NOT WORK

Categories differ in technological complexity, regulatory class, market size and existing capability. The evidence does not support a uniform approach across the MedTech basket.

IMPLICATION Match instruments to category realities. Blanket import substitution will fail on bankability in every category examined.

WHAT THIS MEANS FOR IMPLEMENTATION

The four findings on demand certainty, regulatory cost, industry appetite and supplier upgrading point to the same conclusion: the binding constraints are commercial and administrative. Interventions that reduce uncertainty and cost will outperform interventions that mandate outcomes.

5. RECOMMENDATIONS

The study recommends a capability-led localisation strategy centred on five complementary pathways:

- **Consolidate and scale established manufacturing capability** in categories such as wheelchairs, rehabilitation products, surgical sutures, gloves, medical furniture, sterilisation consumables and intravenous administration sets and infusion consumables where existing production capacity is under-utilised.
- **Deepen manufacturing in partially localised sectors** including advanced wound care, drainage and tubing products within collection devices and electrically actuated ICU beds, advanced examination couches, and electronically controlled patient handling systems, allowing manufacturers to enhance and broaden their product portfolios.
- **Support backward integration by established importers and distributors**, enabling progression from importing to local assembly, component production and manufacturing in categories where production complexity and market demand support localisation including respiratory accessories, syringes and needles, crutches, walkers and walking frames and infusion accessories and moulded components, including injection caps, three-way stopcocks and extension sets.
- **Establish rapid diagnostic test manufacturing as the sole In Vitro Diagnostic (IVD) opportunity**
- **Promote final assembly, servicing, and technical support localisation** for advanced imaging, laboratory and medical equipment where full-scale manufacturing is not commercially viable.

Cross-cutting interventions should focus on meaningful coordinated state procurement, procurement policy reform, demand aggregation, skills development, regulatory support, testing and certification infrastructure, technology partnerships and improved access to finance. Collectively, these interventions can support both healthcare resilience and industrial development objectives while creating a sustainable platform for future growth of South Africa's MedTech sector.

Section 1: Context and Rationale

MedTech products are foundational to healthcare delivery, underpinning prevention, diagnosis, treatment, and rehabilitation. Beyond their health impact, MedTech is strategically significant for South Africa's industrial development, as outlined in the Medical Technology Masterplan.

Localising manufacturing can catalyse broader industrialisation, stimulate enterprise development, and position South Africa as a continental hub for MedTech innovation and supply, aligning healthcare priorities with national development objectives. This section provides the context and rationale for MedTech localisation in South Africa and presents the study methodology, including trade and procurement data analysis, stakeholder consultations, supplier surveys, and evidence triangulation used to identify and prioritise the identified localisation opportunities.

1.1 Background and Rationale

Medical technologies (MedTech) underpin every stage of care from prevention and diagnosis to treatment, monitoring, and rehabilitation. The availability, affordability, and reliability of MedTech directly shape health outcomes and the resilience of health systems. In South Africa, the sector sits at the intersection of public health and industrial development, offering a dual opportunity to strengthen healthcare delivery while stimulating economic growth, innovation, and employment.

South Africa is the largest MedTech market on the African continent. According to the 2022/23 South African Medical Research Council (SAMRC) Medical Devices Landscape Report, drawing on Fitch Solutions estimates, the domestic medical device market was projected to reach approximately R29.6 billion in 2025. Demand continues to grow, driven by population growth, urbanisation, the rising burden of communicable and non-communicable diseases, expanding healthcare services, and technological advances. Yet despite this scale, the country remains heavily dependent on imports, with the SAMRC Medical Devices Landscape Report noting more than 90% of medical devices were sourced internationally, while local manufacturing accounted for less than 5% of domestic market value and barely 0.3% of global sales (Figure 1). This gap between strong demand and limited local manufacturing capacity is the central challenge this study addresses.³

³ These findings align with the representations made by the industry in parliament during the sessions titled, 'Colloquium on South Africa's Industrial Development Strategy (Day 2) with Deputy Minister', available at: https://pmg.org.za/committee-meeting/43448/?utm_campaign=minute-alert&utm_medium=email&utm_source=transactional

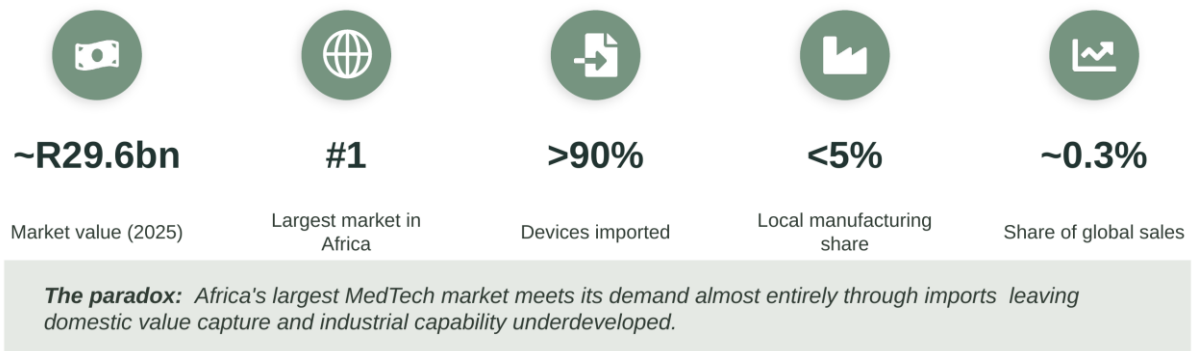


Figure 1: The South African MedTech Paradox

This high level of import dependence carries both economic and health-security risks. The COVID-19 pandemic exposed the vulnerabilities associated with reliance on global supply chains, including shortages of critical medical products, procurement delays, transportation disruptions, export restrictions, and significant cost increases. Dependence on imported medical technologies can also leave countries vulnerable during future pandemics, public health emergencies, or global supply chain disruptions, when international demand surges and access to essential products becomes constrained. Sustained import reliance further limits domestic value creation, constrains industrial development, reduces job creation, and increases exposure to exchange-rate volatility. Together, these risks reinforce the case for strengthening local manufacturing capacity and building a more resilient and self-sustaining local MedTech industry (Figure 2).



Figure 2: Consequences of Import Dependence

As per the SAMRC 2022-23 report citing Fitch Solutions, 2021 annual local manufacturing output was estimated at R3.2-R4.8 billion⁴ and was concentrated in lower-complexity categories such as consumables and disposables, with only niche participation in advanced segments. The sector was dominated by small and medium-sized enterprises, and more than half of the local output was exported rather than

⁴ 1 USD = ZAR 16.103, based on the SARS exchange rate on 31 December 2021.

consumed locally, reflecting persistent difficulties in integrating local manufacturers into national procurement systems and competing with established international suppliers.

PUBLIC SECTOR		PRIVATE SECTOR	
POPULATION SERVED	~80% of citizens	STRUCTURE	Few large hospital & lab groups
DEMAND DRIVER	Volume - largest by units	DEMAND DRIVER	Higher-value technologies
PROCUREMENT BIAS	Price & supply reliability	PROCUREMENT BIAS	Specialist preference, brand, service
LOCALISATION BARRIER	Capacity & pricing concerns	LOCALISATION BARRIER	Accreditation & bundled service models

Figure 3: Market and Drivers

The structure of the healthcare market further shapes localisation prospects. The public sector serves roughly 80% of the population and is the largest source of demand by volume, while the private sector, concentrated among a few large hospital and laboratory groups, drives demand for higher-value technologies. Procurement in both sectors has historically favoured established international suppliers based on price, quality assurance, regulatory compliance, service support, and supply reliability. These preferences, compounded by high certification costs, limited local testing infrastructure, and shortages of specialised skills in areas such as regulatory affairs, quality management systems, conformity assessment, biomedical engineering, product development, advanced manufacturing, validation, and technical service support, form the principal barriers to local manufacturing (Figure 4).⁵



Figure 4: Barriers to Localisation

Recognising both the strategic importance of MedTech and the risks of excessive import dependence, government and industry have increasingly prioritised localisation. The launch of the Medical Technology Masterplan in 2024 marked a decisive step towards strengthening local manufacturing, improving supply security,

⁵ These findings align with the representations made by the industry in parliament during the sessions titled, 'Colloquium on South Africa's Industrial Development Strategy (Day 2) with Deputy Minister', available at: https://pmg.org.za/committee-meeting/43448/?utm_campaign=minute-alert&utm_medium=email&utm_source=transactional

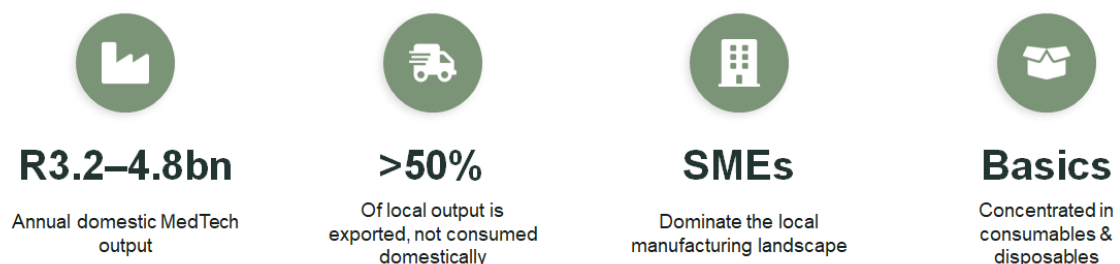
creating jobs, reducing the medical device trade deficit, and fostering a more competitive industry anchored in the lessons of the pandemic on the value of resilient local manufacturing.

Within this context, the Localisation Support Fund (LSF) has played a catalytic role, supporting research and evidence generation to identify viable localisation opportunities across the MedTech value chain. However, despite growing policy attention, substantial information gaps have persisted regarding the size, composition, and localisation potential of specific product categories. The diversity and fragmentation of the market have made it difficult to prioritise investment and policy interventions based on robust evidence.



Figure 5: Policy Momentum: From Untapped Potential to Coordinated Response

The MedTech Demand Mapping Study was therefore undertaken to provide a comprehensive, evidence-based assessment of demand, supply dynamics, and manufacturing feasibility across priority medical technology categories in South Africa. It aims to support strategic decision-making by identifying the product segments with the greatest localisation potential to inform the policies, investments, and partnerships needed to build local capability. Ultimately, localisation seeks to do more than reduce import dependence; it aims to strengthen health-system resilience, improve supply security, stimulate industrial development, and advance South Africa's broader economic transformation objectives, as per the goals of the Industrial Development Strategy (IDS) 2026.



Limited in scale and scope with much of its output leaving the country rather than supplying domestic demand.

Figure 6: A Selective, Evidence-Based Path to Localisation (SAMRC 2022-23)

1.2 Study Objectives

The study is designed to convert South Africa's MedTech demand into an actionable, evidence-based localisation agenda. It pursues three primary objectives and answers four questions: what is procured, where local manufacturing can realistically substitute imports, how much of a market exists, and why local products are or are not currently chosen (Figure 7).



Figure 7: Four Questions That Drive Prioritisation

1. **Map MedTech demand:** Develop a system-wide inventory of the medical devices procured and used across the public and private sectors, identifying what is procured and the import dependence of products. This establishes a baseline of demand across device categories (diagnostics, consumables, surgical instruments, implants, imaging, and others).
2. **Assess local sourcing potential:** For each major category, gauge buyers' willingness and the conditions under which they would procure locally, weighing quality, cost, regulatory, and service requirements. The aim is to isolate the subset of categories where localisation potential is high, demand exists and buyers are open to switching, while flagging categories likely to remain import reliant.
3. **Quantify demand volumes and prices** by attaching quantitative values to the map, such as estimated annual procurement volumes and reference price ranges for priority categories. These figures size the market behind each opportunity and underpin the business case for local manufacturing, distinguishing viable scale from marginal niches. (Figure 8)

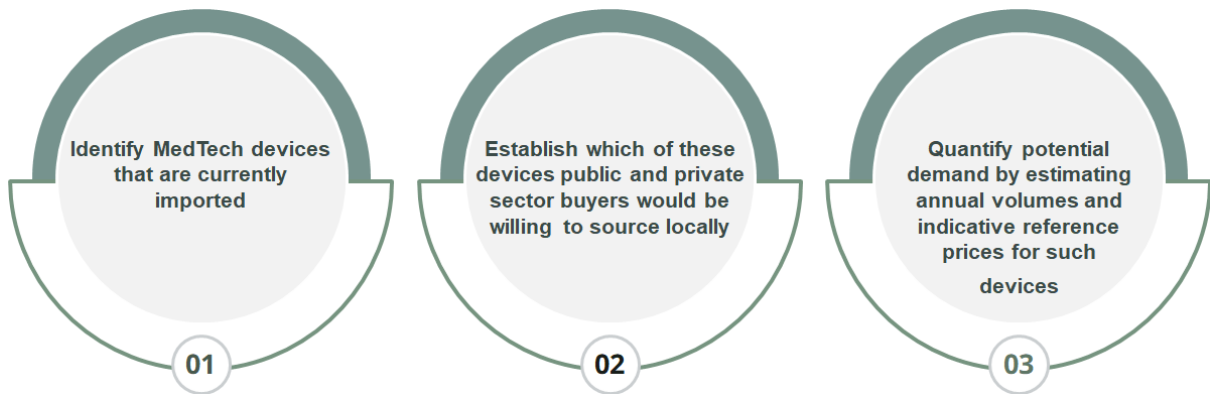


Figure 8: What the Study Sets Out to Achieve

CROSS-CUTTING: Barriers, Enablers & Recommendations - document what constrains local procurement, what could unlock it, and translate the evidence into owner-assigned actions aligned to the Masterplan.

Collectively, these objectives move the analysis from description to decision. Knowing what the demand is, where local manufacturing could feasibly substitute imports, how much of a market exists, and why local products are currently used or avoided allows interventions and investment to be prioritised with confidence and matched to realistic pathways and responsible actors rather than presented as an undifferentiated wish list.

1.3 Methodology and Data Sources

 Trade and Procurement Data Sources	• Data Sources: SARS trade, Stats SA supply and use, National Treasury datasets (LOGIS and BAS), transversal contracts and available reports and publications. • Data Extraction and Analysis: Trade data was analysed by mapping tariff-line imports and exports into product categories and associated values, then assessing each for source-market concentration. Estimates were triangulated against national accounts, treasury datasets and published sources to confirm import dependence and local manufacturing.
 Stakeholder Consultations	• Thirty-five key informant interviews were conducted with a broad range of stakeholders including government consultations at national and provincial level, trade associations and boards, academia, public and private hospitals, suppliers, medical schemes, pharmacies and regulators. Online validation sessions were hosted with industry associations.



Online Supplier Survey

- Resulted in **responses from 27 South African MedTech suppliers**, led by distribution (44%) and full local manufacturing (41%) models, and facilities clustered in Gauteng and Western Cape. The base is mature: two-thirds have 10+ years of local operation and 59% hold Level 1-4 B-BBEE status. Most respondents (85%) are focused on medical devices.



Data Analysis and Triangulation

- Taken together, the trade and procurement datasets allowed demand to be built from two independent directions: imports at the border and payments at the point of purchase anchored to the national accounts, framed by regulatory risk, and validated through stakeholder and supplier engagement. The result is a **robust and triangulated demand picture**.

STAGE 1: TRADE AND PROCUREMENT DATA ANALYSIS

The trade analysis established the quantitative foundation of the demand map. Its aim was to move beyond a headline view of import dependence to a granular, category-by-category reading of what South Africa imports by value, growth trajectory and source market, thereby answering the study's first guiding question ("what is imported and from where") and isolating the segments large or fast-growing enough to justify a localisation case.

The analysis spanned the full breadth of the market, covering both medical devices and in vitro diagnostics (IVDs) and reaching from high-volume consumables through to advanced capital equipment. Trade flows were interrogated at the most disaggregated tariff-line level available and consolidated into a consistent category-and-cluster structure for comparison across the market. The work was national in scope.

The primary analytical window was **2021 to 2025**, chosen to smooth COVID pandemic-related volatility while remaining current. The trade analysis drew on a layered set of official reference sources. Official customs records provided the backbone; national-accounts data supplied cross-checks and an aggregate anchor; and a regulatory framework and published market studies were used for recommendations.

Table 1: Trade Data Sources

Source	Type & role in the analysis	Coverage / window
South African Revenue Service (SARS) trade data	Official import values across MedTech tariff codes; underpins category mapping, import values, country of origin and import concentration index	2021-2025
Statistics South Africa (Stats SA Supply & Use Tables)	- The macroeconomic anchor for the analysis. - Situates imports and domestic output within total supply/demand for medical appliances, enabling the net local-production position to be estimated.	2021-2022 (latest reconciled)
South African Health Products Regulatory Authority (SAHPRA) risk framework	Classification lens. Four-tier Class A-D system (WHO/GHTF-aligned) applied per category to signal regulatory burden and feasibility.	Applied across categories for recommendations
Reference publications	External plausibility checks - South African Medical Research Council (SAMRC) Medical Device Landscape, Trade and Industrial Policy Strategies (TIPS) draft Medical Devices Masterplan Value Chain, Who Owns Whom, Department of Trade, Industry and Competition (DTIC) Medical Technology Masterplan, National Health Laboratory Service (NHLS) annual reports, Council for Medical Schemes (CMS) industry reports and healthcare utilisation annexures.	Triangulation

Whereas the trade analysis captures what enters the country, the demand estimation draws on actual procurement records to establish what the health system genuinely buys, from whom, and at what price. Three public-sector datasets and a set of private-sector signals were used to build this demand-side view, each triangulated against the trade data and stakeholder engagement rather than relied upon in isolation. The

following datasets underpinned the demand-side analysis, combining public procurement records and private signals with stakeholder and supplier validation:

Table 2: Data Sources for Analysis of Procurement

Source	Type & role in the analysis	Coverage / window
National Treasury – Basic Accounting System (BAS) from Procurement Payment Dashboard	Government financial management and payment system capturing actual procurement payments made by national and provincial departments. BAS was used as a validated expenditure dataset to estimate public-sector MedTech spending, analyse expenditure trends and identify spending concentrations across provinces. As BAS records payments only after successful financial processing, it provides a reliable measure of realised procurement expenditure rather than planned or budgeted spending or outstanding payments.	2021 - 2025
National Treasury - Logistical Information System (LOGIS)	Primary public-sector demand dataset. LOGIS is Government's procure-to-pay and supply chain management system, capturing procurement transactions across the full purchasing cycle, including orders, goods receipts, invoices, contracts, and supplier payments. LOGIS provides a more granular view of procurement activity through its Management Information Item Number (MIIN) classification structure, enabling procurement to be analysed at product-category level. This allowed the study to identify demand by specific MedTech categories, analyse procurement trends, assess supplier participation, provincial purchasing patterns, and estimate category-level market demand. The availability of item-level procurement classifications made LOGIS the principal source for constructing the public-sector MedTech demand map and identifying high-value and high-growth localisation opportunities.	2022-2025

National Treasury Transversal Contracts	Strategic procurement and supplier intelligence source used to assess the current supply landscape for MedTech categories. Contract-level information was analysed to determine the country of origin of contracted products, assess the extent of import dependence, and evaluate the presence of local manufacturing capability. The analysis enabled differentiation between suppliers acting primarily as importers/distributors and those undertaking local manufacturing. This information was used to validate localisation opportunities, assess existing local manufacturing capability, identify categories with established local suppliers, and understand the degree to which public procurement is currently supporting South African manufactured products.	All available transversal contracts related to MedTech
---	--	--

The combined use of trade statistics, procurement records, and supplier intelligence allowed demand and supply dynamics to be assessed from both the market and procurement perspectives. Trade data provided visibility into import dependence and sourcing patterns, procurement data revealed actual purchasing behaviour and expenditure priorities, while supplier and contract analysis identified the degree of local manufacturing participation and the origin of products supplied into the healthcare system. Together, these sources were triangulated with stakeholders and survey evidence to generate a comprehensive and validated understanding of market demand, local capability, and localisation potential.

STAGE 2: STAKEHOLDER VALIDATION

The qualitative parameter and stakeholder validation draws on two strands of primary fieldwork - key informant interviews and an online survey.

STAKEHOLDER CONSULTATIONS

Thirty-five (35) key informant interviews (KIIs) were completed across government, regulators, healthcare providers, academia and industry. Adjacent is an overview of the stakeholder outreach and their representation in the KIIs. In addition, online validation sessions were hosted with companies across four industry bodies namely, SAMED (South African Medical Technology Industry Association), SALDA (Southern African Laboratory Diagnostics Association), MDMSA (Medical Device Manufacturers of South Africa), WCMD (Western Cape Medical Devices Cluster), to provide input into product classification, research methodology and preliminary findings. These sessions were well attended by industry leaders.

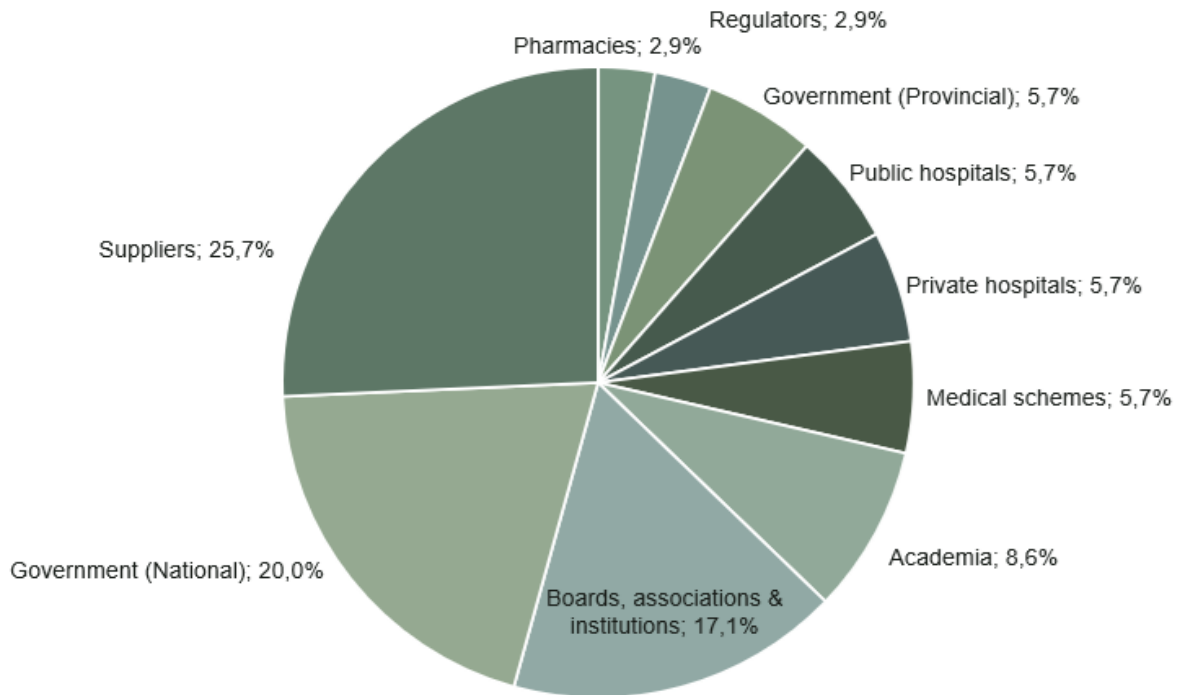


Figure 9: Representation of Stakeholder Groups in Consultations

ONLINE SURVEY

An online supplier survey was conducted using the SurveyCTO platform. Prior to launch, the questionnaire was reviewed by industry stakeholders, whose inputs were incorporated to improve relevance and alignment with sector priorities.

The survey was distributed through recognised trade associations and professional networks, which supported survey dissemination to their members. This approach was intended to maximise industry reach and encourage participation across the South African MedTech ecosystem. The survey remained open for approximately one month and a total of 27 completed responses were received.

The survey findings were not used as a standalone source of evidence but rather as a validation and contextualisation tool within the broader analytical framework. Survey responses were triangulated with trade data, procurement datasets, supplier intelligence, and key informant interviews to assess local manufacturing capability, capacity utilisation, localisation pathways, supply-side constraints, and opportunities for increased local participation in the South African MedTech market.

Overview of Survey Respondents' Profile

Distribution (44%) and full local manufacturing (41%) were the two dominant business models in the survey sample, followed at a distance by import local manufacturing (own brand) and label manufacturing. Only one respondent operated a dedicated research laboratory and only one was a pure pack manufacturer. Most companies (89%) reported a single activity type; only two companies reported two activities, and

one company reported five spanning the full value chain from full local manufacturer through distributor, wholesaler and research lab.

The supplier base was mature with 48% of the companies having operated in South Africa for more than 20 years, and a further 19% for 11-20 years. Two-thirds of the sample have over a decade of local operating history. Only 7% of the companies are true early-stage entrants (<3 years). Full local manufacturers are the most tenured group in the sample, with nearly three-quarters having operated in South Africa for more than 20 years and only one true early-stage entrant, indicating that local manufacturing is a mature, established capability rather than a nascent one still finding its footing. Distributors, by contrast, show the widest spread across tenure bands, ranging from long-standing players of over two decades to newer entrants of three to five years, consistent with distribution being the lowest-barrier way to enter this market (Figure 10). In terms of B-BBEE status, 59% of respondents reported Level 1-4 and a further 26% reported Level 5-8, while 15% of the companies reported non-compliant/exempt status.

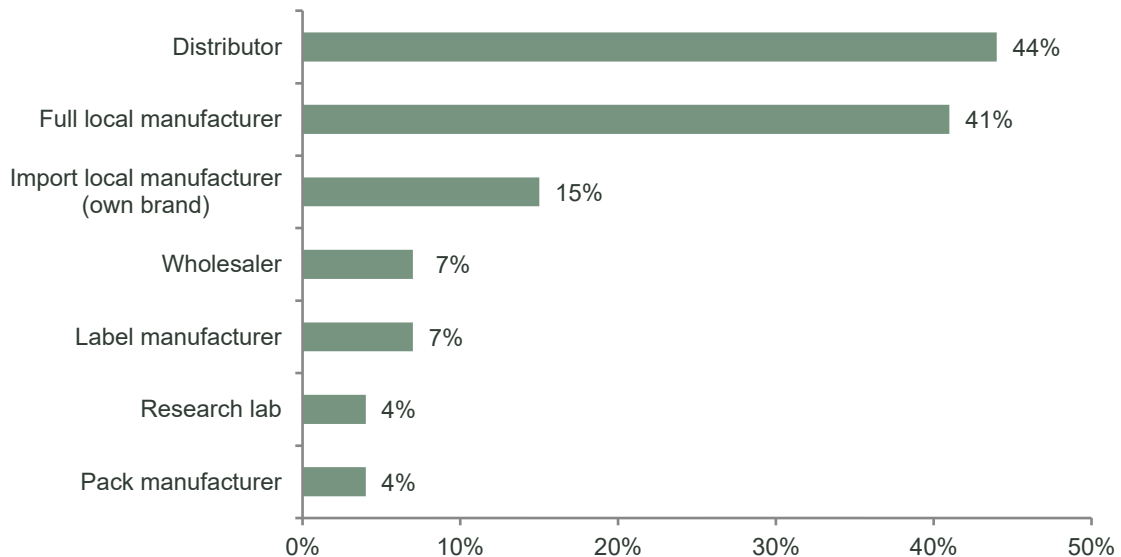


Figure 10: Supplier Survey Respondents' Profile (Multiple choice)

The sample was overwhelmingly Medical Device-weighted: 85% of the companies work primarily in medical devices, 11% span both devices and IVD, and only 4% are IVD-only. Among the 26 device-active companies, product involvement spanned seven main clusters. Medical equipment was the largest (58%), followed by Single use devices (46%) and Implantable devices (42%). Imaging, Software, PPE, and Surgical/laboratory instruments were the smallest clusters, each represented by around 12-15% of companies.

STAGE 3: PRIORITISATION, EVIDENCE SYNTHESIS AND DATA TRIANGULATION

The final stage of the study integrated evidence from multiple, independent data sources to identify the MedTech product categories with the strongest and most realistic localisation potential. Prioritisation was based on structured triangulation of both qualitative and quantitative evidence streams. Refer to Figure 11 for data sources and integration framework.

Demand mapping: Public-sector demand was assessed using a combination of LOGIS, BAS procurement data and NHLS annual reports and Council for Medical Schemes (CMS) industry reports and healthcare utilisation annexures. LOGIS served as the primary demand-mapping source due to its granular product-category and supplier-level visibility, while BAS provided a complementary view of overall public-sector expenditure patterns and provincial spending concentrations. In addition, NHLS annual reports provided valuable insights into public-sector IVD demand through test volumes and provincial revenue trends, while the CMS healthcare utilisation annexure offered perspectives on private-sector utilisation patterns and the disease burden driving demand for diagnostics, particularly for chronic diseases and ongoing disease management.

- **Trade exposure:** These demand signals were assessed against SARS trade data to flag categories combining high import dependence, sustained or growing demand and supplier concentration.
- **Feasibility:** National Treasury transversal contracts and supplier information were reviewed to determine country of origin, distinguish imported from locally manufactured products, map existing local manufacturing capability, and identify where current suppliers could credibly expand into adjacent categories.
- **Primary data and existing literature:** Supplier survey, key informant interviews, initial validation workshops and literature added insights into international trends, manufacturing readiness, production capacity, procurement preferences, policy and regulatory constraints, and localisation barriers that transactional data alone cannot capture.

A category was prioritised as a priority only where evidence converged across these independent sources, specifically: consistent evidence of meaningful and sustained market demand; sustained import dependence; existing or credibly expandable local manufacturing capability; a feasible regulatory pathway; and stakeholder support for localisation. A category strong on one dimension but unsupported on another (e.g. a large addressable market with no manufacturing capability or no regulatory pathway) was not prioritised.

Results of various stakeholder inputs, including the interview, validation and survey material were examined through a structured thematic analysis rather than treated as a set of isolated views. A predefined set of analytical domains, aligned with the study

objectives and refined as the engagements progressed, provided a consistent lens across all respondents and allowed patterns to be identified within and across stakeholder groups. Interviews were recorded with participant consent, transcribed to create a complete and verifiable qualitative dataset, and coded against these domains, which are summarised below in Table 3.

Table 3: Key Themes for Localisation Analysis

Analytical domain	What it examined
Demand and sourcing behaviour	How public, private and retail buyers currently purchase, and the extent to which sourcing decisions favour or exclude local manufacturers.
Local capability and capacity	The maturity, footprint and spare capacity of local manufacturers, and the value-chain segments in which they already participate.
Barriers to localisation	Structural, regulatory, commercial and skills-related constraints that limit local manufacturing and market access.
Enablers and good practice	Existing levers and emerging practices, from procurement design to certification support, that demonstrably strengthen local participation.
Localisation pathways and willingness	The route to localisation considered as most viable for each category, and buyer and supplier willingness to move up the value chain.

The stage concluded by translating this evidence into sequenced, actionable recommendations. Consistent with the study's purpose of informing implementation of the Medical Technology Masterplan, the recommendations were framed around a small set of coordinated levers, spanning procurement and demand signalling, regulatory and certification enablement, manufacturing capability and skills, data and market intelligence, and public-private collaboration and risk management, and were aligned with the Masterplan's working pillars so that each can be taken forward by an identifiable owner.

MedTech Demand Mapping - Data Sources & Integration Framework

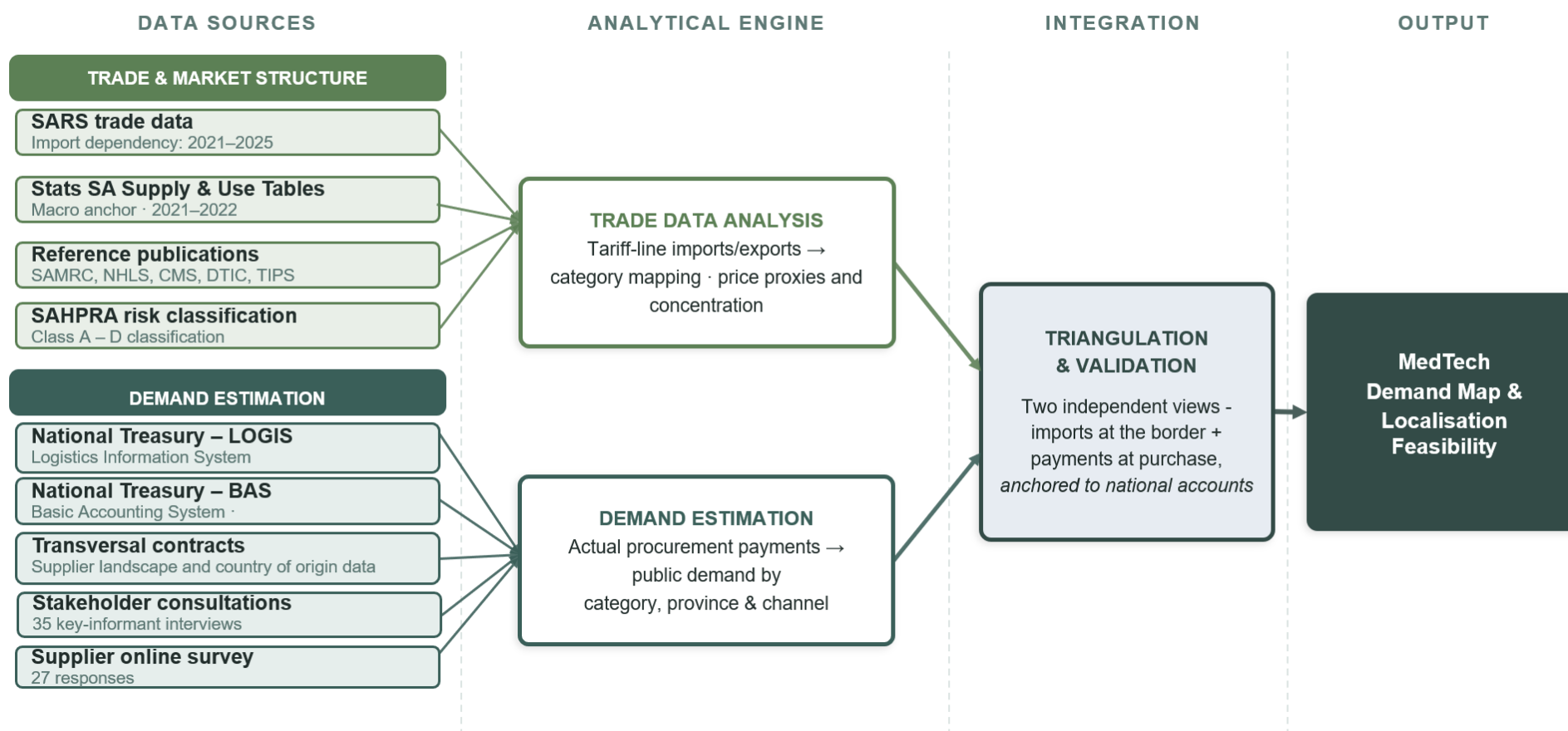


Figure 11: Evidence Synthesis and Data Triangulation

LIMITATIONS AND INTERPRETATION GUIDANCE

The study draws on a diverse range of data sources; however, the following limitations should be considered when interpreting the findings:

- **SARS trade data granularity:** SARS trade statistics are reported at HS tariff-code level rather than individual product level. A single tariff code may include multiple products and, in some cases, non-healthcare items. For example, laboratory equipment tariff codes may include equipment used beyond healthcare settings, limiting precise product-level analysis.
- **Supply and Use Table classification:** Statistics South Africa Supply and Use Tables provide a useful macro-level view of the medical appliances sector; however, the dataset does not clearly specify which MedTech products are included within the medical appliances classification. It was used as a directional validation source rather than a product-level market measure.
- **BAS expenditure data:** While the BAS provides a reliable record of realised public-sector expenditure and is valuable for estimating overall MedTech spending and provincial expenditure patterns, it is a financial management system rather than a product-level procurement database. Expenditure classifications are often aggregated and do not consistently provide the level of product detail required to identify specific devices, quantities procured, or supplier-level purchasing patterns.
- **LOGIS coverage and comparability:** While LOGIS provides valuable item-category level procurement information, it does not comprehensively capture procurement across all provinces and departments. Notably, Gauteng, one of the largest healthcare procurement markets based on BAS expenditure data, represents a relatively small share of recorded LOGIS spend. In addition, LOGIS provides only partial visibility of IVD procurement, and total procurement values are substantially lower than BAS records, meaning the two datasets are complementary but not directly comparable.
- **NHLS procurement data:** The NHLS procurement dataset was not included in the analysis presented in this report. The dataset represented only a limited sample of procurement transactions and was therefore not considered sufficiently representative of overall public-sector IVD procurement activity.
- **Private-sector visibility:** The private-sector market, comprising major hospital groups such as Netcare, Mediclinic and Life Healthcare, and large pathology providers including Lancet Laboratories, Ampath and PathCare, has limited publicly available information on procurement and utilisation patterns. In addition, private-sector procurement data is not centrally available and remains commercially sensitive. As a result, private-sector demand assessment relied on publicly available market information, limited procurement signals, and stakeholder

engagement, and should therefore be interpreted as indicative rather than exhaustive.

- **Local manufacturing data availability:** No comprehensive national dataset exists on MedTech manufacturing output, production capacity, or local market share. Assessments of local capability therefore relied on transversal contracts, supplier surveys, stakeholder consultations, and secondary research.
- **Supplier classification and value chain positioning.** A key limitation of the analysis was the lack of sufficiently detailed and consistently reported data across the available literature, databases and industry sources to accurately classify suppliers according to their position within the MedTech value chain. In particular, it was not possible to reliably distinguish between full local manufacturers, assemblers, contract manufacturers, importers with local value addition, distributors, wholesalers and purely imported-product suppliers. As a result, the analysis of the MedTech market and localisation landscape should be interpreted with caution, as the available evidence does not permit a comprehensive assessment of the level of local manufacturing contribution or value addition across different supplier categories.
- **Impact of COVID-19 on import, demand and supply estimates.** Data utilised for this analysis includes information from 2021 and 2022, which coincided with the COVID-19 pandemic and subsequent recovery period. The pandemic resulted in substantial disruptions to global and local medical device supply chains, procurement patterns and healthcare utilisation, while simultaneously increasing demand for selected product categories such as diagnostics, personal protective equipment, infection prevention products, ventilators and other critical care devices. Consequently, market size, import volumes, local manufacturing activity and supplier participation reported during these years may not fully reflect normal market conditions. Findings related to supply, demand and market dynamics for specific product categories should therefore be interpreted with caution, recognising that some estimates may have been temporarily inflated or distorted by pandemic-related factors.
- **Survey response rate.** The survey was distributed through major industry associations and 27 responses were received. The survey findings should therefore be viewed as directional and interpreted alongside other data sources.
- **Limited availability of quantity-based procurement data:** Procurement records often captured expenditure values without corresponding unit volumes, making it difficult to accurately quantify the number of devices procured and compare procurement volumes across provinces. As a result, demand estimation was undertaken primarily on the basis of expenditure and procurement transaction data, supplemented by available volume information in NHLS annual reports.
- **Data reporting periods:** Although the study focuses on the period **2021–2025**, the underlying datasets were derived from multiple sources with differing reporting

periods, financial years, contract durations, and publication cycles. Consequently, not all data sources were directly comparable or fully aligned to the study timeframe.

To mitigate these limitations, findings were systematically triangulated across trade data, procurement records, transversal contracts, supplier surveys, stakeholder consultations, regulatory frameworks, and published literature to develop a robust and evidence-based assessment of MedTech demand and localisation opportunities.

Section 2: Market Structure and Trade Analysis

This section examines the structure of South Africa's MedTech market and the trade dynamics shaping it, drawing on SARS trade data and Statistics South Africa supply-and-use tables. It presents overall market size and growth, cluster-level demand, and import trends, quantifying the scale of import dependence and isolating the segments large or fast-growing enough to anchor a localisation case.

KEY TAKEAWAYS

Structurally import-dependent market: Roughly 80% of medical appliances available in South Africa are sourced from imports, with the import share of total supply rising from 78.1% to 80.8% between 2021 and 2022.⁶

Strong demand growth: Total supply grew ~18%, from R57.2 billion (2021) to R67.5 billion (2022) at base price, while total use rose from R69.5 billion to R84.4 billion at purchasers' price, yet the increase was met predominantly through imports rather than local manufacturing.

Stagnant local manufacturing: Local manufacturing grew only marginally, from R12.5 billion to R12.9 billion, with its share of supply falling from 21.9% to 19.2%, highlighting limited local capacity to meet rising demand.

High-value import concentration: MedTech imports totalled approximately R155 billion between 2021 and 2025, with the United States alone accounting for 70.7% of total import value, concentrated in advanced, high-complexity technologies.

Surgical instruments dominate imports: Surgical and Medical Instruments is the single largest imported category at R34.0 billion, reinforcing its strategic importance to the healthcare system.

Split sourcing pattern: China leads on the number of imported product categories, which are concentrated in consumables, rehabilitation products, dressings and syringes while technologically advanced equipment remains heavily sourced from the United States and Germany.

Supplier concentration risk: Several product categories depend on a narrow supplier base.

⁶ StatsSA Supply and use tables

2.1 Medical Appliances Market Size and Growth (Supply and Use Tables, 2021-2022)



Figure 12: Overview of MedTech Market Size and Growth

Between 2021 and 2022, South Africa's medical appliances sector became increasingly dependent on imports despite growth in domestic production. Total supply at basic prices increased from R57.2 billion in 2021 to R67.5 billion in 2022, representing growth of approximately 18%. Over the same period, imports rose from R44.7 billion to R54.6 billion, increasing their share of total supply from 78.1% to 80.8%, while domestic production grew only marginally from R12.5 billion to R12.9 billion, reducing its share from 21.9% to 19.2%. This indicates that rising demand for medical appliances was met predominantly through imports rather than local manufacturing (Figure 12).

On the demand side, total use at purchasers' prices increased from R69.5 billion to R84.4 billion, driven primarily by higher industry consumption, which rose from R24.3 billion to R30.9 billion and accounted for approximately 35% to 37% of total demand, reflecting increased utilisation by hospitals, clinics, laboratories, and other healthcare providers. Exports grew from R9.0 billion to R12.7 billion, increasing their share of total use from 13% to 15%. Overall, the supply and use tables show a structurally import-dependent market in which approximately 80% of medical appliances available in South Africa are sourced from imports, while domestic production remains insufficient to meet the growing requirements of healthcare service delivery, capital investment, and export demand (Figure 13).

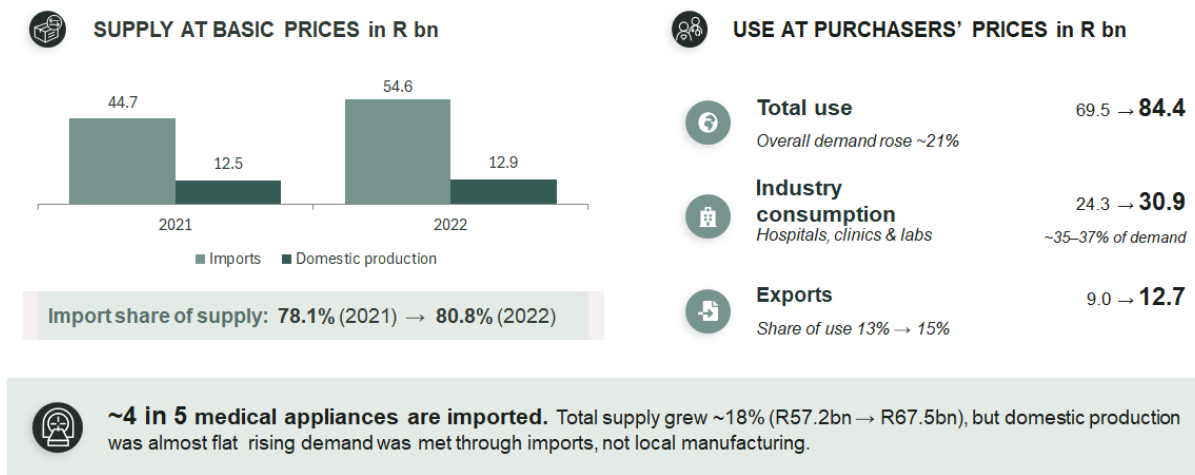


Figure 13: Import-Dependent Market

2.2 Cluster-level Analysis

IMPORT ANALYSIS - SARS DATA

South Africa's MedTech import profile highlights a healthcare sector that remains highly dependent on imported medical technologies, with imports valued at approximately R155 billion between 2021 and 2025, of which the United States accounts for 70.7% of the total import value. This level of dependence is particularly pronounced in high-value categories such as surgical and medical instruments, laboratory equipment, orthopaedic products, artificial joints, catheters, ophthalmic instruments, and diagnostic technologies, where developed manufacturing markets continue to dominate supply.

At R34 billion, Surgical and Medical Instruments is the largest imported MedTech category, reinforcing its strategic importance within the healthcare system. While China leads the highest number of product categories, its dominance is concentrated mainly in consumables, rehabilitation products, dressings, syringes, and other lower-complexity devices, whereas technologically advanced equipment remains heavily sourced from the United States and Germany. A notable feature of the market is the presence of supplier concentration risk, with several product categories being dependent on a small number of countries or suppliers. For example, wheelchairs show very high market concentration (HHI 0.62) with China supplying approximately 78% of import value, while rehabilitation devices, gloves, blood-grouping reagents, contact lenses, and dental chairs also exhibit elevated concentration levels, indicating limited supplier diversity. The data therefore suggests that although South Africa benefits from access to advanced global medical technologies, significant opportunities exist for localisation and supplier diversification, particularly in

consumables, basic surgical instruments, dressings, medical furniture, and selected rehabilitation products, where dependence on a narrow supplier base remains high (Figure 14).

South African MedTech imports by product category, 2021–2025

Total imports
R155.68bn

United States leads
70%
of value · 13 lines

China leads
18
lines · 14% of value

Most concentrated
HHI 0.62
Wheelchairs · China 78%

LEADING SOURCE COUNTRY BY SHARE OF IMPORT VALUE

United States 69.8%						14.4%		5.8%		9.6%	
		China		Germany		Others					
PRODUCT CATEGORY	R MILLION	CAGR	SOURCE	HHI	PRODUCT CATEGORY	R MILLION	CAGR	SOURCE	HHI		
Surgical and medical instruments	34,293.8	+9%	USA	28%	0.12	MRI systems	1,205.9	+16%	DEU	44%	0.26
Other IVD reagents and test kits	23,681.1	+1%	USA	49%	0.26	Tubular metal needles	1,112.5	+5%	CHN	19%	0.10
Laboratory equipment	15,181.7	+11%	USA	30%	0.13	Contact lenses	1,010.8	+11%	GBR	51%	0.32
Catheters, cannulae and tubes	10,110.3	+17%	USA	24%	0.10	Rehabilitation devices	924.7	+6%	CHN	69%	0.49
Orthopaedic and fracture appliances	7,078.9	+9%	USA	44%	0.23	Ostomy products	831.3	+4%	HUN	42%	0.26
Artificial joints	5,537.9	+10%	USA	36%	0.20	Dental fillings and cements	798.1	+13%	DEU	31%	0.17
Other electrodiagnostic equipment	4,504.3	+16%	CHN	23%	0.13	Culture media	756.9	-7%	FRA	27%	0.16
General prosthetic devices	4,269.4	+4%	USA	32%	0.14	X-ray tubes	729.6	+7%	USA	40%	0.23
Respiratory therapy equipment	3,633.6	-2%	CHN	24%	0.11	Dental prosthetics	622.6	+3%	n/s		—
Other artificial body parts	3,353.2	+22%	USA	34%	0.15	Sterilisers	490.2	-8%	CHN	24%	0.11
X-ray systems	3,153.0	+4%	DEU	29%	0.17	Electrocardiographs	384.4	+1%	DEU	25%	0.14
Ophthalmic instruments	2,684.7	+4%	USA	26%	0.14	Dental X-ray systems	298.1	+3%	FRA	22%	0.17
Non-adhesive dressings	2,302.4	+13%	CHN	35%	0.18	Medical X-ray film	294.1	-16%	JPN	20%	0.53
Hearing aids	2,279.9	+12%	DNK	18%	0.13	Wheelchairs, non-mechanical	292.8	+7%	CHN	72%	0.53
Adhesive dressings	2,179.7	+15%	CHN	37%	0.19	Blood grouping reagents	286.3	+18%	CHE	60%	0.40
Medical furniture	2,063.4	+1%	CHN	34%	0.18	Dental chairs	229.9	+17%	CHN	51%	0.31
Spectacle lenses	2,057.9	+3%	THA	45%	0.26	Dental wax	229.9	+6%	CHN	38%	0.22
Imaging parts and components	1,997.0	+7%	DEU	26%	0.12	Surgical and OT lights	212.8	+5%	DEU	31%	0.19
Contraceptives	1,869.1	+7%	IND	31%	0.23	UV and infrared systems	184.7	+11%	USA	27%	0.15
Contrast media	1,797.8	+14%	IRL	30%	0.18	Contact lens solution	177.8	+14%	ITA	39%	0.25
Gloves	1,781.5	-16%	MYS	63%	0.44	Wheelchairs, mechanical	134.9	+3%	CHN	78%	0.62
Sutures	1,575.9	+17%	USA	35%	0.17	Gel preparations	130.7	+23%	CHN	23%	0.13
Syringes with or without needles	1,381.1	+0%	CHN	33%	0.17	Radiotherapy systems	130.2	+54%	NLD	34%	0.19
CT scan apparatus and accessories	1,334.9	+19%	CHN	40%	0.23	Scintigraphy apparatus	126.3	+93%	ISR	27%	0.20
Dental hand instruments	1,296.1	+7%	DEU	31%	0.15	First aid boxes and kits	84.3	+1%	CHN	77%	0.61
Ultrasound systems	1,278.2	+15%	CHN	27%	0.17	Dental drill systems	43.8	+23%	CHN	73%	0.19
Pacemakers	1,253.1	+6%	CHE	38%	0.25	Malaria diagnostic kits	26.6	+61%	USA	46%	0.27

VALUE CONCENTRATES IN THE UNITED STATES

CHINA LEADS THE COMMODITY LINES

Figure 14: Product Level Analysis of Import Value and Countries of Import

*HHI - The index with a value between 0 and 1 shows the degree of geographical concentration of the international goods trade. It is also known as the Herfindahl-Hirschman Index (HHI). The index is calculated by squaring the shares of the individual countries in total imports of a specific product and then summing them. The stronger the link of specific product trade is with only a limited number of countries and therefore the stronger the geographical concentration, the higher the index. The market is not concentrated if the index lies below 0.15, somewhat concentrated with an index from 0.15 to 0.25 and concentrated when the index is 0.25 or higher.

Section 3: Demand Estimation

This section quantifies the underlying demand and localisation strategy required to serve the public sector, drawing on public procurement data from BAS and LOGIS. It analyses expenditure by product segment, province, and over time to identify areas where demand is largest, growing most rapidly, and sufficiently concentrated to support a compelling investment case.

KEY TAKEAWAYS

Large public-sector market: Public-sector MedTech procurement (BAS) totalled approximately R50.3 billion between 2021 and 2025, confirming the scale of demand underpinning the localisation case.

Geographic concentration: Gauteng (36%), Western Cape (18%) and KwaZulu-Natal (13%) together account for 67% of public procurement spend, concentrating demand in the most developed healthcare markets.

Imaging leads spend: Medical diagnostic imaging and nuclear medicine products are the single largest BAS segment at 23.8% (R11.96 billion), followed by medical equipment and accessories at 18.2% (R9.14 billion).

Strong localisation opportunities in selected categories: Triangulation of LOGIS procurement data and National Treasury transversal contracts highlights several product categories that combine substantial and growing public-sector demand with existing local manufacturing capability, including sutures, assistive products, medical furniture, dressings, respiratory accessories, IPC products and selected consumables.

Provincial IVD demand concentration: Public-sector IVD demand is concentrated in Gauteng and KwaZulu-Natal, which lead all provinces on both NHLS revenue and test volumes.

Stable, high-volume test base: The NHLS's highest-volume tests have stayed the same over recent years, dominated by routine chemistry and haematology, alongside HIV viral load and TB molecular testing.

Import dependence: South Africa depends heavily on imported IVD products. The national testing platforms come from multinational manufacturers, and local manufacturing is limited to a few firms producing rapid tests and molecular reagents.

3.1 Total Procurement Value

3.1.1 KEY FINDINGS FROM PROCUREMENT PAYMENT DATA FROM BAS

Public sector MedTech procurement in South Africa totalled approximately R50.3 billion between 2021 and 2025, with procurement activity concentrated in a small number of provinces. Gauteng emerged as the dominant procurement market, accounting for 36% of total expenditure (R17.9 billion), followed by the Western Cape (18%) and KwaZulu-Natal (13%). Collectively, these three provinces represented 67% of total procurement spending, highlighting a strong concentration of healthcare purchasing activity in South Africa's most developed healthcare markets. A second tier comprising Eastern Cape (8%), Limpopo (6%), Mpumalanga (6%), and North West (6%) contributed a combined 26% of expenditure, while Free State (4%) and Northern Cape (2%) accounted for relatively small shares (Figure 15).

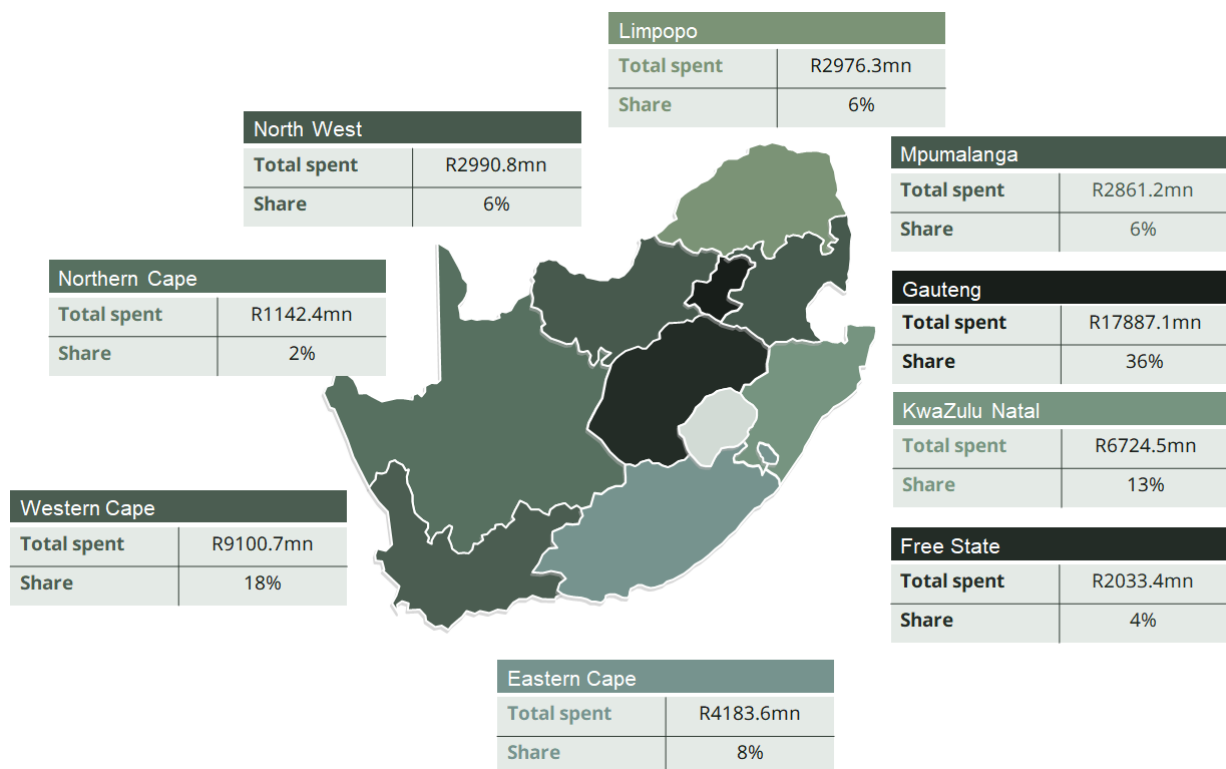


Figure 15: Geographic Spread of Procurement Spend

Medical diagnostic imaging and nuclear medicine products represented the largest procurement segment, accounting for 23.8% (R11.96 billion) of total expenditure, highlighting the priority placed on diagnostic infrastructure and imaging services. This was followed by Medical Equipment and Accessories and Supplies at 18.2% (R9.14 billion), reflecting broad-based demand for healthcare equipment and consumables

across healthcare facilities. Surgical products accounted for 9.5% (R4.76 billion), while Bandages, dressings and related products (7.1%), Orthopaedic surgical implants (6.8%), and Neurosurgical implants (6.6%) together represented a significant share of procurement, underscoring the importance of surgical and trauma-related healthcare services. Other notable categories included medical gases (5.5%) and medical diagnostic X-ray products (5.4%), further reinforcing the emphasis on acute care and diagnostic capabilities (Figure 16).

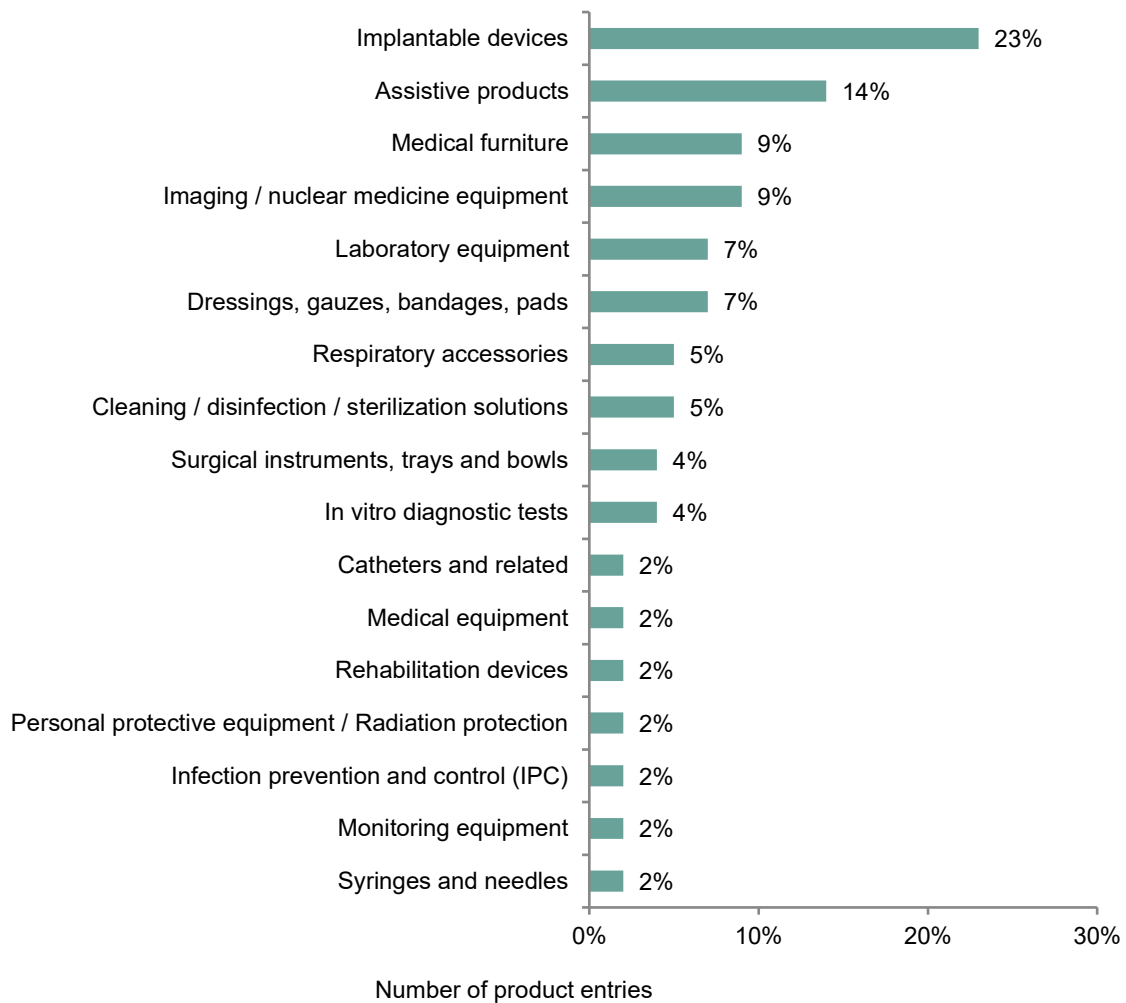


Figure 16: Procurement Share of Devices (in %)

The BAS procurement data indicates that Gauteng, Western Cape, and KwaZulu-Natal are the principal drivers of public-sector MedTech demand, collectively accounting for approximately R33.7 billion in procurement expenditure. Across these provinces, spending was concentrated in medical diagnostic imaging and nuclear medicine products (R6.8 billion) and medical equipment, accessories and supplies (R6.2 billion). Surgical products (R3.7 billion), orthopaedic surgical implants (R2.5 billion), and medical diagnostic X-ray products (R2.4 billion) also represented significant demand areas. Notably, IVD- and laboratory-related procurement formed

an important component of spending, including laboratory dialysis supplies (R0.56 billion), manual test kits, quality controls and calibrators (R0.24 billion), point-of-care testing supplies and equipment, and laboratory and scientific equipment. This highlights continued investment in diagnostic testing, laboratory operations, quality assurance, and patient monitoring capabilities alongside imaging infrastructure (Figure 17).

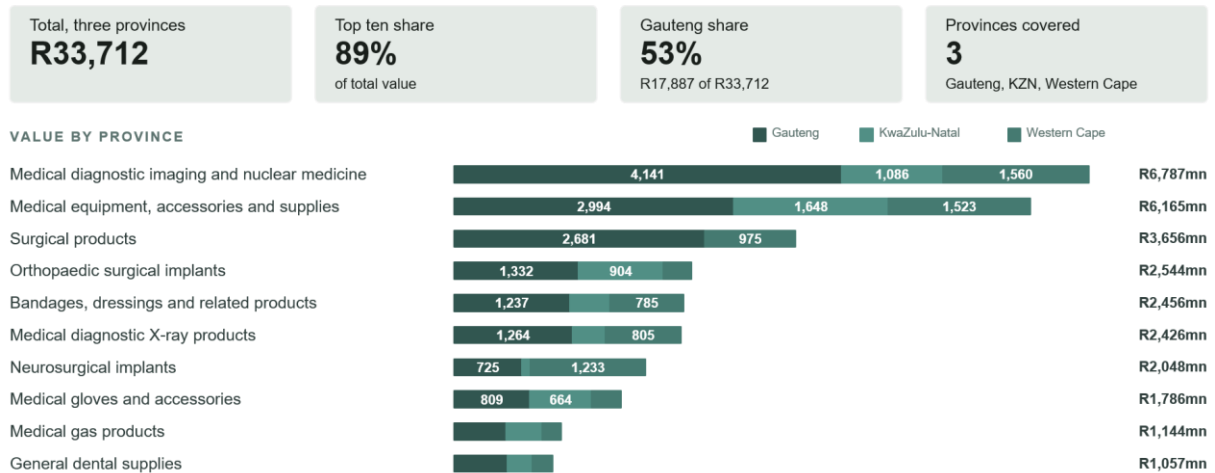


Figure 17: Proportion of Procurement of Devices in Three Provinces

3.1.2 KEY FINDINGS FROM PROCUREMENT DATA THROUGH LOGIS

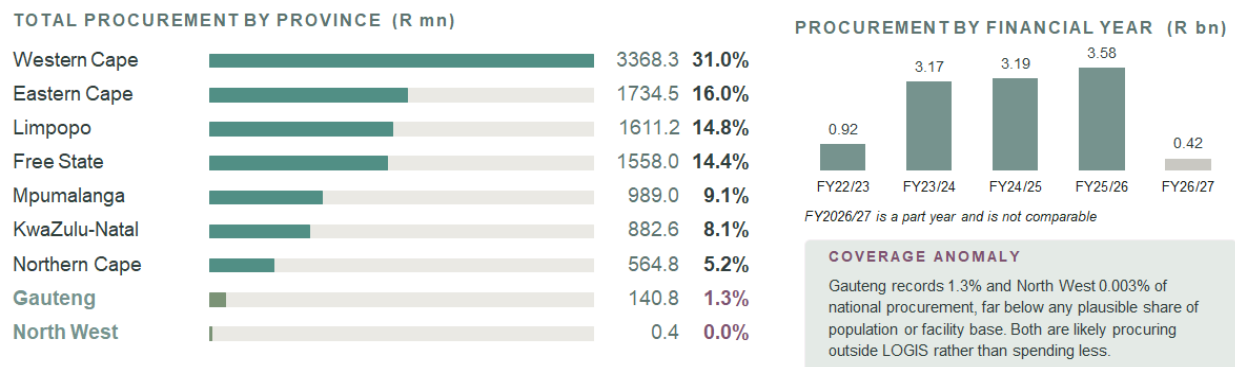


Figure 18: Value of Procurement at Provincial Level

Procurement was highly concentrated, with the Western Cape emerging as the largest market, accounting for R3.37 billion (31.0%) of total expenditure, followed by the Eastern Cape (R1.73 billion, 16.0%), Limpopo (R1.61 billion, 14.8%), and Free State (R1.56 billion, 14.4%). Together, these four provinces accounted for approximately 76% of total procurement spending, highlighting the concentration of demand in a limited number of provinces (Figure 18).

Medical Equipment (R1.32 billion; 12%) and Imaging and Nuclear Medicine Equipment (R1.14 billion; 11%) together accounted for almost a quarter of total procurement expenditure, reflecting continued investment in healthcare infrastructure, diagnostics,

and capital equipment. Other major expenditure categories included Dressings, Gauzes, Bandages and Pads (8%), Monitoring Equipment (8%), Implantable Devices (7%), and Assistive Products (6%), demonstrating significant demand across both acute-care and patient-support segments. Notably, several categories associated with stronger localisation potential, including assistive products, IPC products, surgical instruments, medical furniture, respiratory accessories, collection devices, tubing products, and catheters, collectively accounted for a substantial share of procurement expenditure, indicating meaningful market opportunities for local manufacturers. Overall, the LOGIS data highlights a procurement landscape characterised by strong demand for both advanced medical technologies and high-volume consumable products (Figure 19).

IVD and laboratory-related procurement represented an important component of public-sector MedTech expenditure, totalling approximately R353.6 million between FY2022/23 and FY2025/26. This comprised In Vitro Diagnostic (IVD) Tests valued at R226.2 million and Laboratory Equipment valued at R127.4 million. While the overall share of laboratory-related procurement remains modest relative to high-spend categories such as medical equipment, imaging, and implantable devices, both segments demonstrated strong growth, with IVD tests increasing at a CAGR of 26% and laboratory equipment at 62% CAGR. The procurement pattern indicates sustained investment in diagnostic and laboratory capacity across the public healthcare system, reflecting growing demand for disease diagnosis, screening, monitoring, and laboratory services (Figure 19).

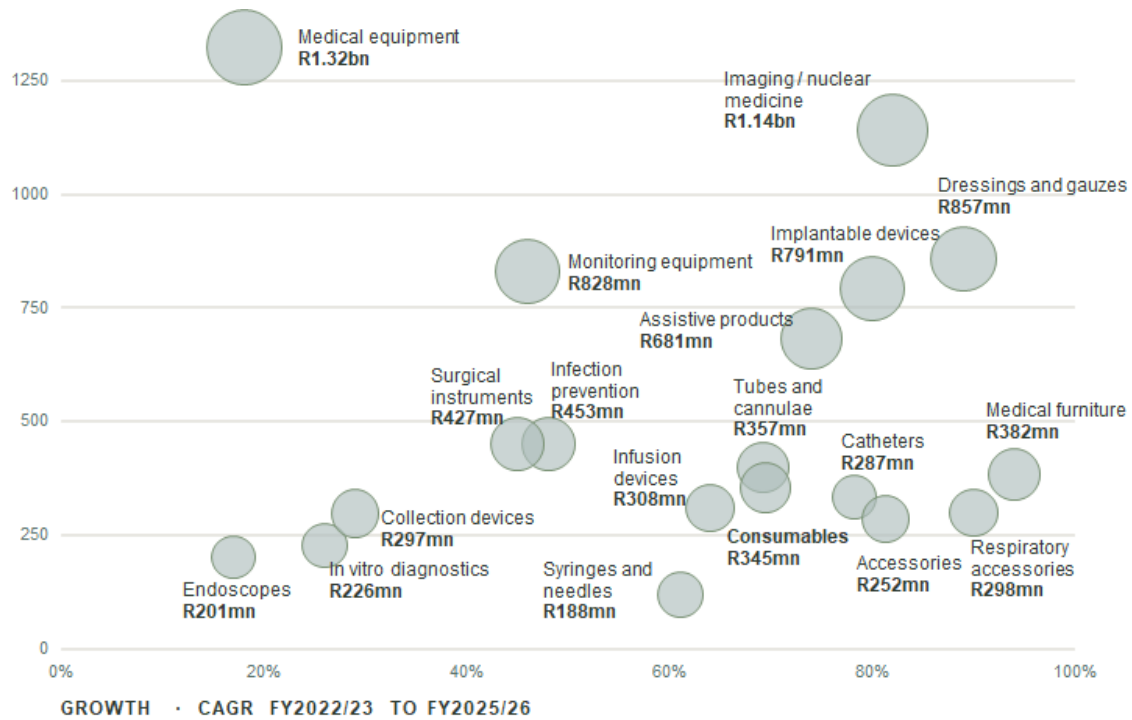


Figure 19: Cumulative Spend on Each Device Category

Category Level Analysis – LOGIS data

Catheters and related

Total expenditure
R287.9mn
FY2022/23 – FY2025/26

Growth
80%
CAGR over four years

Top ten supplier share
61%
Moderate concentration

Import dependency
High
No local manufacture identified

IMPORT DEPENDENCE

The market is import-led rather than manufacturing-led. Although most contracted suppliers are South African registered entities, they function as distributors and importers rather than original manufacturers.

High

Leading suppliers Teleflex Medical 15% · B. Braun Medical 9% · DPR Pharmaceuticals 8%

Tubes and cannulae

Total expenditure
R357.8mn
FY2022/23 – FY2025/26

Growth
76%
CAGR over four years

Top ten supplier share
64%
Moderate concentration

Import dependency
High
Distributor-led supply base

IMPORT DEPENDENCE

Supply is import-led. The two largest suppliers hold 35% of expenditure, and the supplier base combines multinational subsidiaries with South African distributors importing globally manufactured product.

High

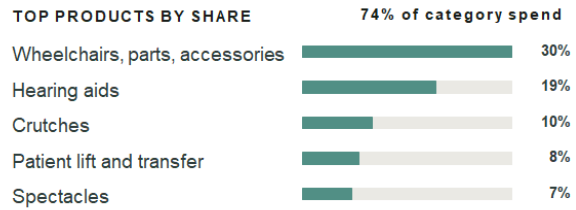
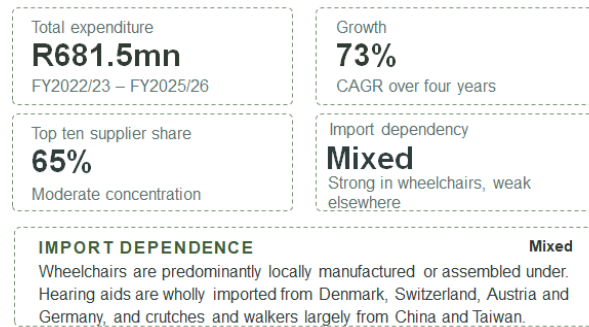
TOP PRODUCTS BY SHARE

46% of category spend

Intravenous cannulae 26%
Nasal cannulae 20%

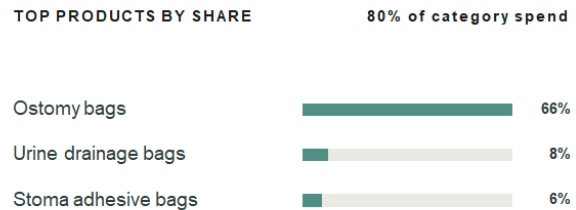
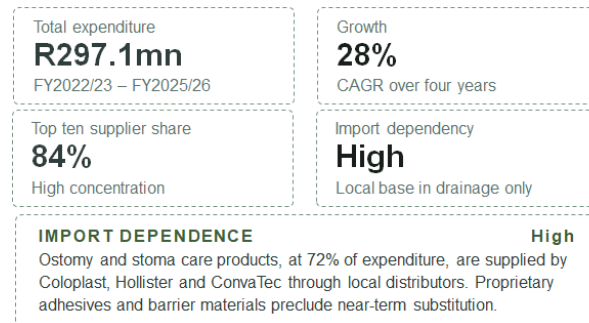
Leading suppliers: Respiratory Care Africa 19% · B. Braun Medical 16% · Akacia Medical 5%

Assistive products



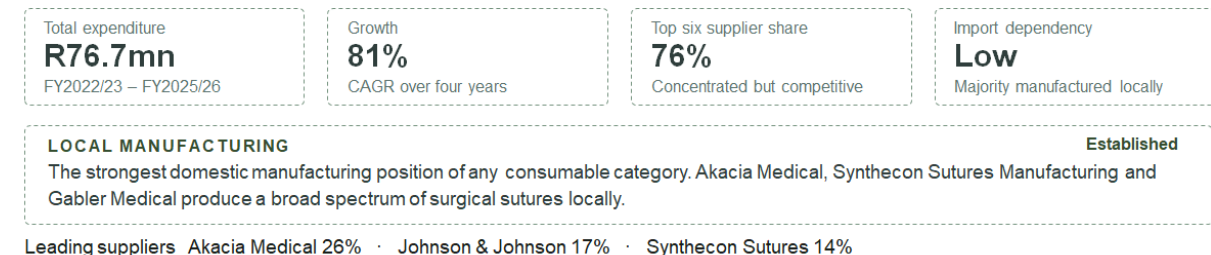
Leading suppliers CE Mobility 21% · Batho Kopanang 7% · Thokomala Mobility 7%

Collection device

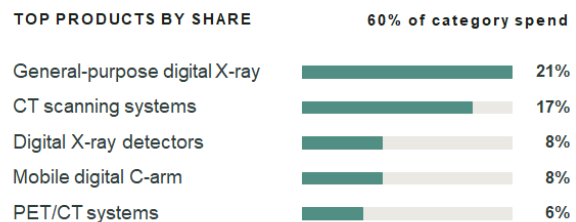
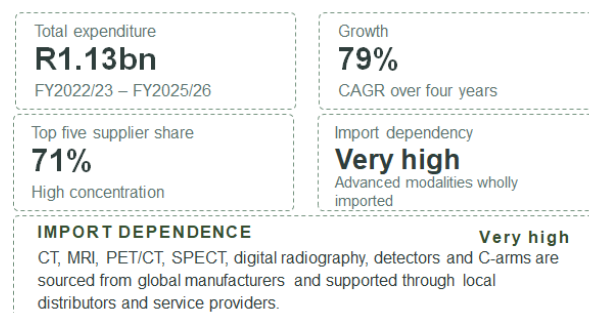


Leading suppliers OMS Medical 33% · Hartmann-Vitamed 19% · Coloplast 10%

Sutures

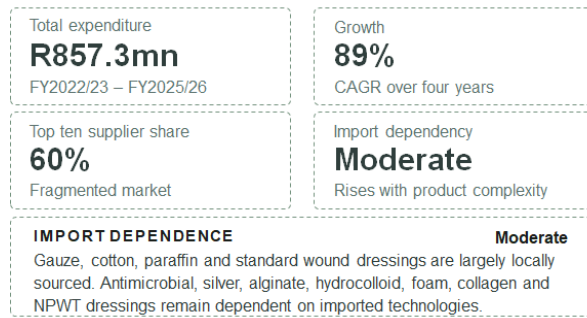


Imaging / nuclear medicine equipment



Leading suppliers Siemens 21% · Tecmed 18% · Lomaen Medical 13%

Dressings, gauzes, bandages, pads



TOP PRODUCTS BY SHARE 82% of category spend

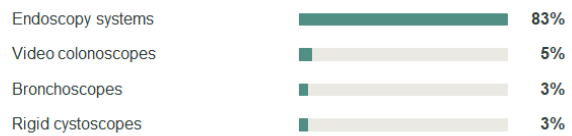


Leading suppliers Akacia Medical 9% · National Pride 9% · BMS Medical Supplies 9%

Endoscopes and related device

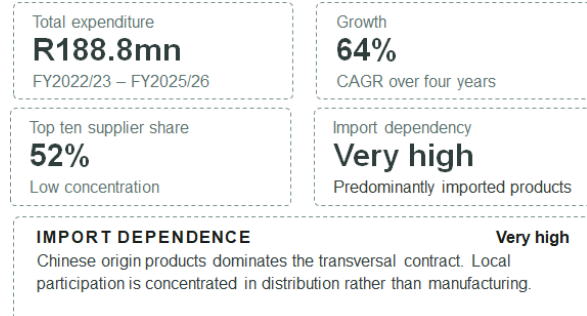


TOP PRODUCTS BY SHARE 94% of category spend

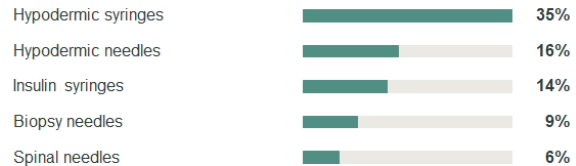


Leading suppliers Karl Storz Endoscopy SA 40% · Tecmed 22% · Grobir Medical 11%

Syringes and Needles



TOP PRODUCTS BY SHARE 80% of category spend

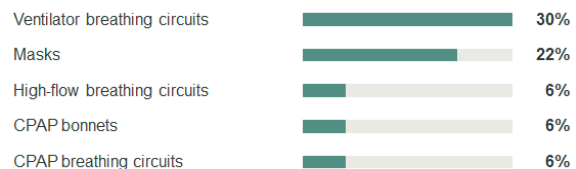


Leading suppliers Becton Dickinson 16% · Embecta South Africa 7% · Medi-Core Technologies 5%

Respiratory care accessories



TOP PRODUCTS BY SHARE 70% of category spend



Leading suppliers Respiratory Care Africa 38% · SSEM Mthembu Medical 18% · Mbuso Medical 4%

In Vitro Diagnostics

Total expenditure R353.6mn FY2022/23 – FY2025/26	Growth 26% CAGR over four years
Top ten supplier share 75% High concentration	Import dependency High Analyser-bound consumables
IMPORT DEPENDENCE High Most suppliers are distributors of multinational diagnostic manufacturers. Reagents, cartridges and cuvettes are proprietary to imported analysers and cannot be substituted without replacing the instrument.	

TOP PRODUCTS BY SHARE 79% of category spend

Clinical chemistry rapid and POC	50%
Haematology reagents	29%

Leading suppliers Promed 23% · HemoCue SA 12% · Tara Healthcare 8%

Infection prevention and control

Total expenditure R453.6mn FY2022/23 – FY2025/26	Growth 49% CAGR over four years
Top ten supplier share 67% High concentration	Import dependency Moderate Surgical gloves locally made
LOCAL MANUFACTURING Established Slightly over half of contracted supply is South African, through Medtex SA and Evergreen Latex. Surgical gloves are overwhelmingly local; examination gloves are predominantly imported.	

TOP PRODUCTS BY SHARE 89% of category spend

Examination gloves	37%
Surgical gloves	31%
Surgical drapes	10%
Sanitary wipes	8%
Masks	3%

Leading suppliers Medtex SA 38% · Promed Technologies 10% · Logan Medical & Surgical 6%

Medical furniture

Total expenditure R382.5mn FY2022/23 – FY2025/26	Growth 100% CAGR over four years
Top ten supplier share 77% High concentration	Import dependency Low Two thirds locally manufactured
LOCAL MANUFACTURING Strong Fabricated steel products are almost entirely local, alongside mechanical ward beds, examination couches and mattresses, through New Horizon Metals, Hospital Equipment Manufacturers and Hospi-Furn.	

TOP PRODUCTS BY SHARE 86% of category spend

Medical beds	51%
Trolleys	13%
Medical tables	12%
Carts	5%
Mattresses	5%

Leading suppliers Arjo Huntleigh South Africa 46% · Kwa-Dube Medical 5% · Hospi-Furn 4%

Medical equipment

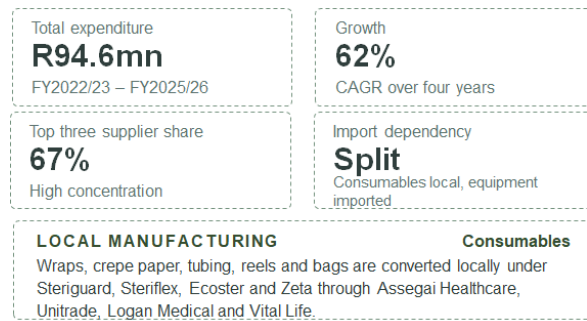
Total expenditure R1.31bn FY2022/23 – FY2025/26	Growth 14% CAGR over four years
Top ten supplier share 68% Moderate concentration	Import dependency Very high % local origin in tender
IMPORT DEPENDENCE Very high Local participation is confined to refrigeration cabinets and two simple mechanical devices. No item incorporating sensing, software-controlled actuation or regulated measurement is domestically produced.	

TOP PRODUCTS BY SHARE 54% of category spend

Ventilators	21%
Infant incubators	10%
Anaesthesia systems	9%
CPAP systems	7%
Radiant warmers	7%

Leading suppliers Class Three Medical 13% · Respiratory Care Africa 12% · Ecomed Medical 10%

Cleaning / Disinfection / Sterilisation Equipment

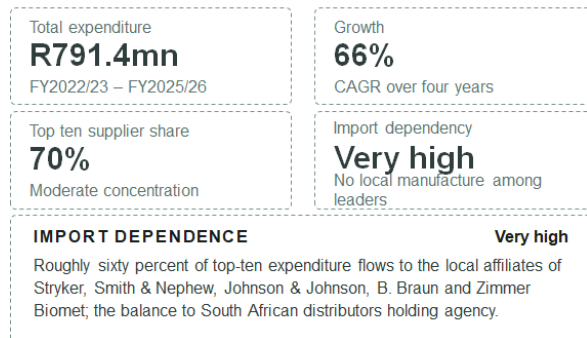


TOP PRODUCTS BY SHARE 89% of category spend

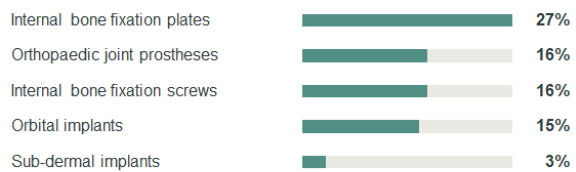


Leading suppliers Medi-Clave 36% Safmed 21% Logan Medical & Surgical 10%

Implantable devices

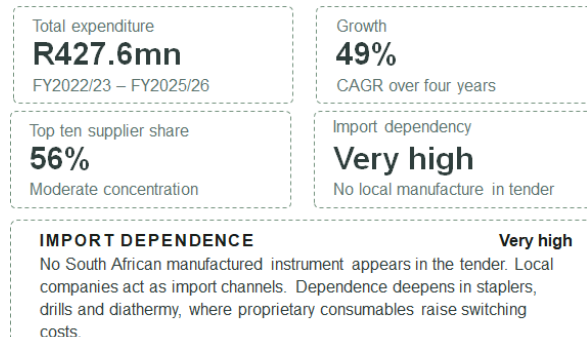


TOP PRODUCTS BY SHARE 77% of category spend



Leading suppliers Stryker South Africa 14% Smith & Nephew 12% Safarmex 9%

Surgical instruments, trays and bowls



TOP PRODUCTS BY SHARE 47% of category spend



Leading suppliers Grobir Medical 11% B. Braun Medical 9%

3.1.3 MAPPING SOUTH AFRICA'S IN VITRO DIAGNOSTICS LANDSCAPE: EVIDENCE FROM PUBLIC AND PRIVATE SECTORS

The National Health Laboratory Service (NHLS) is the backbone of public-sector diagnostics in South Africa. Through its countrywide network of quality-assured laboratories, the NHLS is the sole provider of diagnostic pathology services to more than 80% of the South African population. It serves the entire public sector, from academic, tertiary, regional and district hospitals to primary healthcare facilities. Laboratory complexity increases from peripheral laboratories to central urban laboratories.

NHLS⁷ activity is concentrated in Gauteng and KwaZulu-Natal, which lead every other province on both revenue and test volumes in all years reported. In 2024/25 they generated R3.38 billion and R3.09 billion in revenue and performed 30,967,325 and 27,870,532 tests respectively, more than double any other province, while the Northern Cape remained the smallest (R180 million; 2,053,019 tests). Revenue broadly follows where testing takes place, but the two do not move in step. Between 2022/23 and 2024/25, revenue rose in eight of nine provinces, and it rose in KwaZulu-Natal and the Free State even though test volumes fell. Limpopo and Mpumalanga grew on both measures, while the Western Cape was the only province where both declined. Test volumes peaked in most provinces in 2023/24 before dropping in 2024/25. For IVDs this makes Gauteng and KwaZulu-Natal the decisive markets for high-throughput platforms and reagent volumes. Faster-growing provinces such as Limpopo and Mpumalanga signal expanding service coverage (

Figure 20 and Figure 21).

⁷ Revenue figures are taken from the NHLS national footprint figure in each annual report, where they are reported as “Total Revenue” for each province. Most of this revenue comes from rendering of services, so the figures serve as a proxy for provincial revenue. They may also include other income allocated to the regions, such as government grants and subsidies, donor grant income, antivenom sales and revenue of the national institutes.

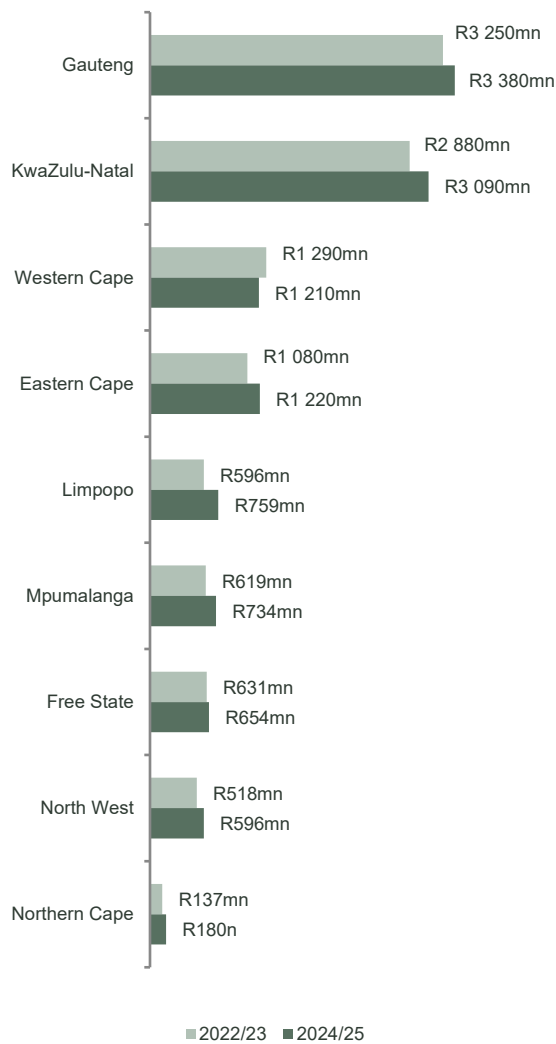


Figure 20: NHLS Revenue in R mn (Source: NHLS annual reports)

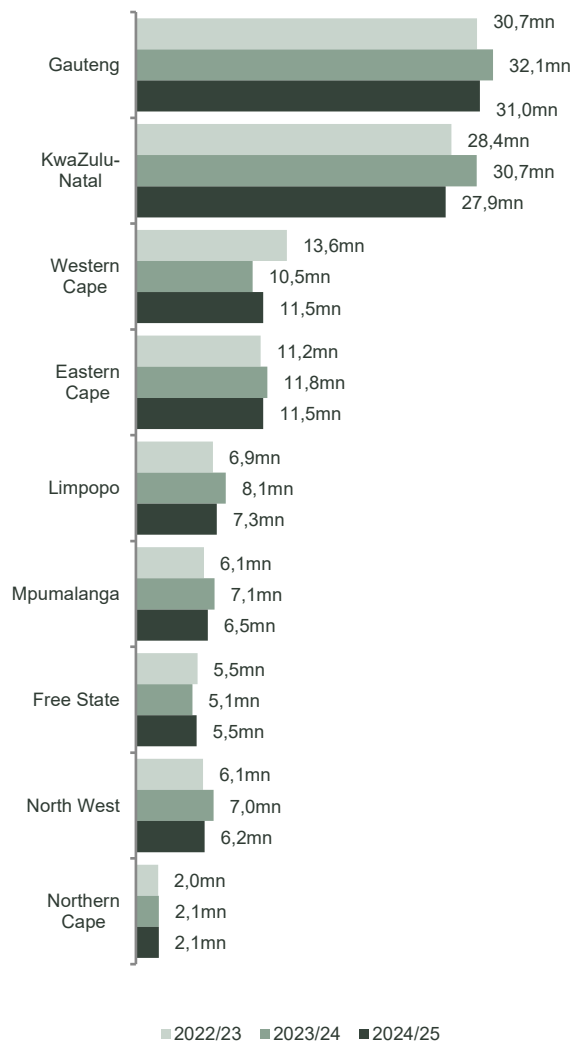
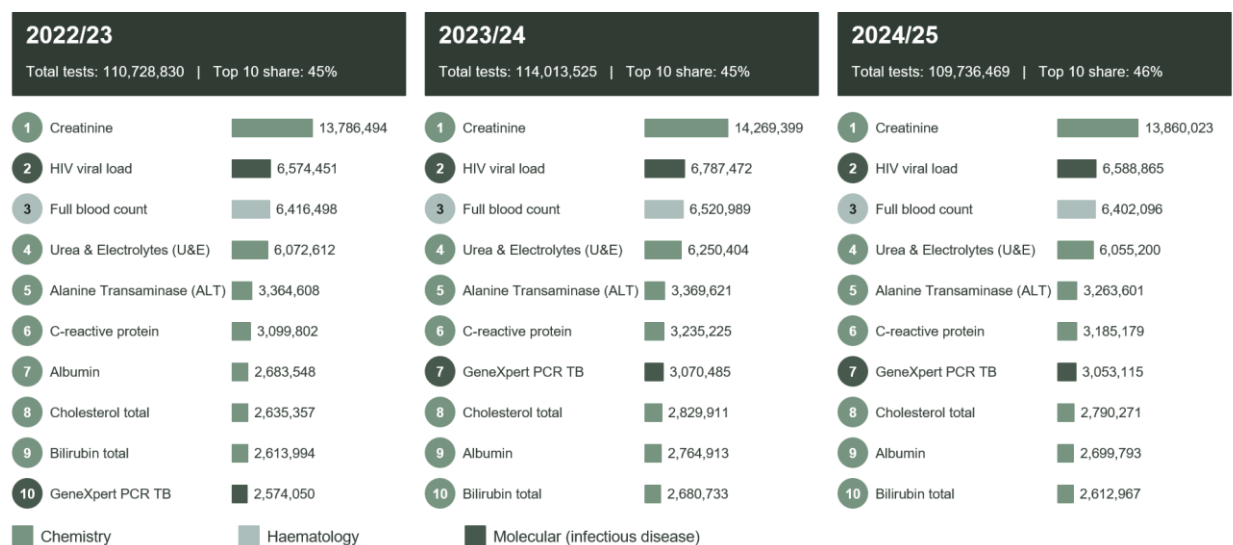


Figure 21: Total Test Volume by Provinces in Million (Source: NHLS annual reports)

Between 2022/23 and 2024/25, the NHLS top 10 tests by volume remained unchanged, collectively accounting for 45% of all tests in 2022/23 and 2023/24 and 46% in 2024/25. The portfolio was dominated by routine chemistry and haematology tests, with creatinine consistently representing the largest test category at approximately 13% of total NHLS volumes (13.8 million in 2022/23, 14.3 million in 2023/24, and 13.9 million in 2024/25). HIV viral load, full blood count and urea and electrolytes consistently ranked second to fourth, respectively, across the three years. The remaining top-volume tests included alanine transaminase, C-reactive protein, cholesterol, albumin, bilirubin and GeneXpert TB PCR. GeneXpert TB was the only test to record a notable shift in ranking, increasing from tenth place in 2022/23 (2.57 million tests) to seventh place in 2023/24 (3.07 million) and maintaining this position in 2024/25 (3.05 million), reflecting expanded uptake of molecular TB diagnostics. All top 10 tests experienced lower volumes in 2024/25 relative to 2023/24, consistent with the decline in total NHLS testing volumes from 114.0 million to 109.7 million tests

following the June 2024 cyberattack. Overall, the testing profile indicates that public-sector IVD demand is driven primarily by high-volume clinical chemistry and haematology assays, complemented by large-scale molecular testing programmes for HIV and TB (Figure 22).



*Number of tests, as reported; ranked by volume within each year.

Figure 22: NHLS Top 10 Tests by Volume, 2022/23 – 2024/25

As per the Council for Medical Schemes (CMS) Healthcare Utilisation Annexures 2024⁸, pathology services, reported under Discipline 52 (Pathology Independent Practice Specialist), represent a substantial and expanding component of private healthcare spending. In 2024, medical schemes paid R15.4 billion in pathology benefits, a 10.3% increase from R14.0 billion in 2023. Consequently, pathology's share of total scheme expenditure increased from 5.84% to 5.94%, while annual pathology expenditure per beneficiary rose from R1,543 to R1,691. In addition, beneficiaries incurred R2.67 billion in out-of-pocket pathology expenditure, reflecting continued reliance on diagnostic testing beyond scheme reimbursements.

Analysis of healthcare utilisation patterns indicates that this demand is increasingly driven by the growing burden of chronic disease among insured beneficiaries. Between 2023 and 2024, treated prevalence increased across all major chronic conditions, including hypertension, hyperlipidaemia, type 2 diabetes, HIV/AIDS, and chronic renal disease. As these conditions require routine laboratory monitoring through HbA1c testing, lipid profiling, renal function assessment, and HIV viral load testing, rising disease prevalence translates directly into sustained demand for clinical

⁸ CMS pathology benefits are payments by medical schemes to pathology practices (Discipline 52) for services rendered, as reported in the CMS Healthcare Utilisation Annexures 2024. They are an indicator of private-sector testing activity and of the underlying demand for IVD products, rather than a measure of IVD product expenditure.

chemistry, immunoassay, and molecular diagnostics. Infectious disease testing also remains an important driver, with HIV testing rates increasing by 9.4% to 37.2 per 1,000 beneficiaries in 2024, although confirmed TB diagnoses declined by 18.1% in 2024 as compared with 2023.

Despite growing disease burden and increasing expenditure, significant gaps remain in the uptake of guideline-recommended diagnostic monitoring. CMS coverage indicators show that fewer than half of beneficiaries with diabetes received recommended HbA1c or lipid testing, with only 42.6% of patients with type 2 diabetes receiving at least two HbA1c tests annually and 42.9% receiving LDL or lipogram testing. Coverage was even lower among beneficiaries with type 1 diabetes (38.2% and 35.3%, respectively). Similar gaps were observed for cardiovascular and renal monitoring, with only 50.9% of patients with hypertension receiving cholesterol testing, 39.0% of those with ischaemic heart disease receiving LDL monitoring, and 36.6% of patients with chronic renal disease undergoing urine protein assessment. While coverage for renal monitoring in diabetes (69.0%) and congestive heart failure (67.5%) was comparatively higher, it remained below optimal levels. These findings highlight a substantial level of unmet diagnostic need within an already insured population, suggesting that actual testing demand could increase considerably if adherence to recommended monitoring guidelines improves. From an IVD market perspective, this represents a significant growth opportunity for laboratories and diagnostic suppliers, particularly in chronic disease monitoring segments such as diabetes, cardiovascular disease, and renal health.

Triangulated evidence indicates that reagents and consumables account for a substantial share of IVD market value, driven by the recurring use of assay kits, reagents, controls, calibrators, molecular testing cartridges, test strips, and other single-use diagnostic inputs. Infectious disease testing, particularly molecular testing for HIV and TB, is a high-value area, sustained by the national viral load and GeneXpert programmes in the public sector and by ongoing HIV monitoring among insured patients. Routine clinical chemistry and haematology generate high test volumes. At the same time, chronic disease monitoring for hypertension, diabetes, lipid disorders and renal disease is driving growing private-sector pathology spending, supporting sustained demand for chemistry, immunoassay and molecular reagents.

The South African IVD market is served mainly by multinational manufacturers, including Abbott, Roche, Siemens, Beckman Coulter, Cepheid, Becton, Dickinson and Company (BD) and others. Across the NHLS annual reports for 2022/23 to 2024/25, a small group of multinational manufacturers consistently supply the platforms and consumables behind South Africa's national public-sector testing programmes. Abbott is the main supplier for HIV viral load testing (Alinity m) and also provides chemistry and immunology analysers. Roche supplies early infant HIV diagnosis (cobas 5800/6800/8800) and TB molecular testing (cobas MTB and MTB-RIF/INH), and previously supported HIV viral load testing (cobas 8800). Cepheid provides the widely used GeneXpert system for TB testing (Xpert MTB/RIF Ultra), and Becton, Dickinson

and Company supplies TB molecular testing (BD MAX MDR-TB). Beckman Coulter supplies CD4 testing (Aquios). Because each programme runs on a specific supplier's platform and consumables, these manufacturers hold established positions in the public sector, supported by their installed base, reagent supply and service networks.

Local IVD manufacturing in South Africa is limited and centred on rapid tests and molecular reagents. The best documented examples are Medical Diagnostech (Cape Town), which makes lateral flow rapid tests for HIV, malaria and pregnancy; LifeAssay Diagnostics (Cape Town), which makes lateral flow and urinalysis tests; and CapeBio, an ISO 13485-certified biotechnology company that makes enzymes, nucleic acids and oligonucleotides for molecular diagnostics.

Section 4: Implications for Localisation

This section translates the study's demand and supply evidence into practical localisation implications, profiling where local manufacturing capability exists, the barriers and enablers shaping it, and the product categories best suited to local manufacturing. It sets out feasible localisation pathways, priority devices, and the coordinated policy and market actions needed to convert demand into sustainable local manufacturing, based on available evidence.

KEY TAKEAWAYS

Findings from primary survey

- **SME-dominated manufacturing base:** Local manufacturing is concentrated among SMEs in lower-complexity, high-volume products, while capital-intensive imaging and implantable devices remain overwhelmingly imported.
- **Manufacturing clusters geographically:** Gauteng and the Western Cape dominate activity- the Western Cape leads full local manufacturing while Gauteng anchors distribution and logistics as per the survey respondents' profile.
- **Significant idle capacity:** Around 47% of local manufacturers operate at 50% capacity utilisation or below, signalling scope to scale import substitution without major new investment.
- **Cost and regulation are the top barriers:** High input costs (68%) and regulatory burden (61%) are the leading constraints, followed by skills gaps (38%) and limited access to finance (36%).
- **Public sector is the hardest market:** 63% of suppliers rate the public sector as the toughest customer segment, driven mainly by payment delays (56%) and lengthy procurement and tender processes (44%).
- **Quality and certification support are critical enablers:** Testing and certification support (57%), CAPEX for equipment and cleanrooms (48%) and quality-system funding (48%) are the most-cited enablers of localisation.
- **Pathways differ by category:** Full local manufacturing is most viable for dressings, respiratory accessories, IPC products, PPE and assistive products, while advanced technologies suit assembly, servicing and refurbishment.
- **Clear priority devices for local content:** Sutures, wheelchairs and assistive devices, gloves, sterilisation consumables, hospital furniture and IV/infusion sets are prime candidates for coordinated state procurement.

4.1 Local Manufacturing Priorities and Capabilities

4.1.1 LOCAL MANUFACTURING AND TRADE SPLIT

The South African MedTech industry is predominantly composed of SMEs, with a limited number of established firms demonstrating advanced manufacturing capability in niche segments. Local companies participate in the market through a combination of full manufacturing, partial assembly, packaging, distribution, and aftersales service provision, rather than end-to-end production across all product categories. This structure reflects both the historical evolution of the sector and the economic realities of competing with large-scale global original equipment manufacturers (OEMs).

Manufacturing capability is most pronounced in lower-complexity, high-volume products, where production processes are relatively standardised, regulatory pathways are manageable, and capital intensity is lower. These characteristics align with South Africa's existing industrial base, skills profile, and cost structure. In contrast, capital-intensive and high-risk devices, particularly advanced diagnostic imaging and implantable technologies, remain overwhelmingly imported, with limited prospects for full local manufacturing under current conditions.

Localisation Clusters: Key Provinces

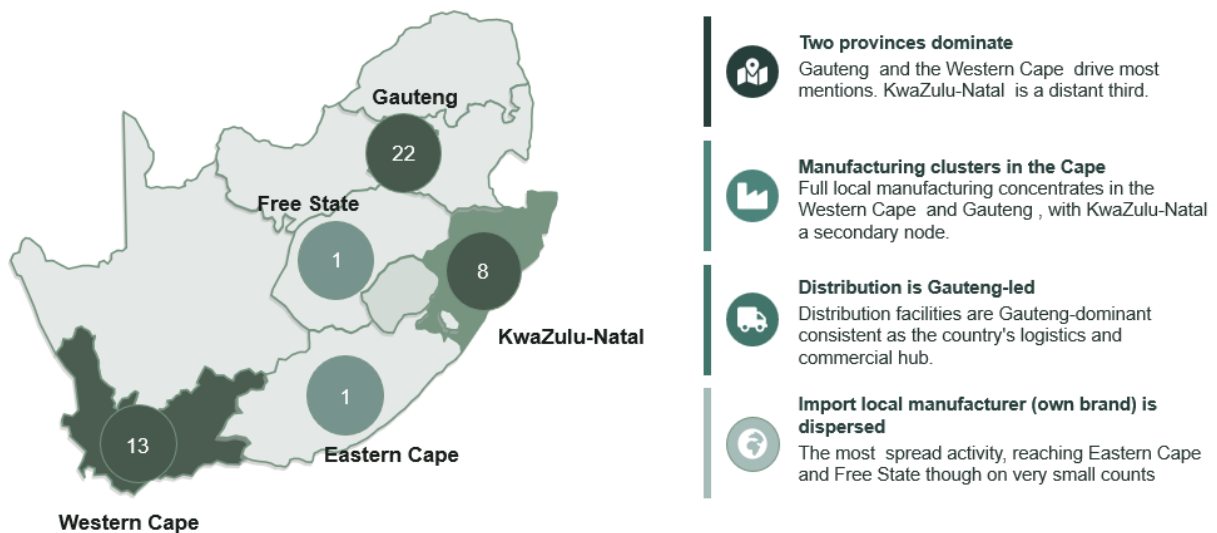


Figure 23: Key Provinces where Localisation Clustered

Data from the supplier survey indicates that Gauteng (22 mentions) and Western Cape (13) together account for the large majority of all facility mentions across every activity type; KwaZulu-Natal (8) is a distant third.

- Full local manufacturing facilities cluster in the Western Cape (6 mentions) and Gauteng (4), with KwaZulu-Natal as a secondary node (3) - Western Cape edges out Gauteng specifically for manufacturing (as opposed to distribution).
- Distribution facilities are Gauteng-dominant (8 mentions) - consistent with Gauteng's role as the country's logistics and commercial hub rather than a specialist manufacturing centre.
- Import local manufacturer (own-brand) activity is the most geographically dispersed of any activity type, with a presence recorded in the Eastern Cape and Free State alongside Gauteng and Western Cape - though on very small counts (1 mention each) (Figure 23).

Medical technology product cluster

Among the 26 device-active companies, product involvement spans seven main clusters. Medical equipment is the largest (58%), followed by Single use devices (46%) and Implantable devices (42%). Imaging, Software, PPE, and Surgical/laboratory instruments are the smallest clusters, each represented by around 12-15% of companies. Test kits (including rapid diagnostic/point-of-care tests) is the most-cited IVD type, with Reagents, Instruments/Analysers, Calibrators & Controls and Specimen Collection each cited once.

Product level market analysis

Implantable devices are the most commonly reported product category (23%), followed by Assistive products (14%), together making up over a third of all responses. Categories like IVD, monitoring equipment, and syringes/needles appear too infrequently to draw firm conclusions and would benefit from a larger sample in future research (Figure 24).

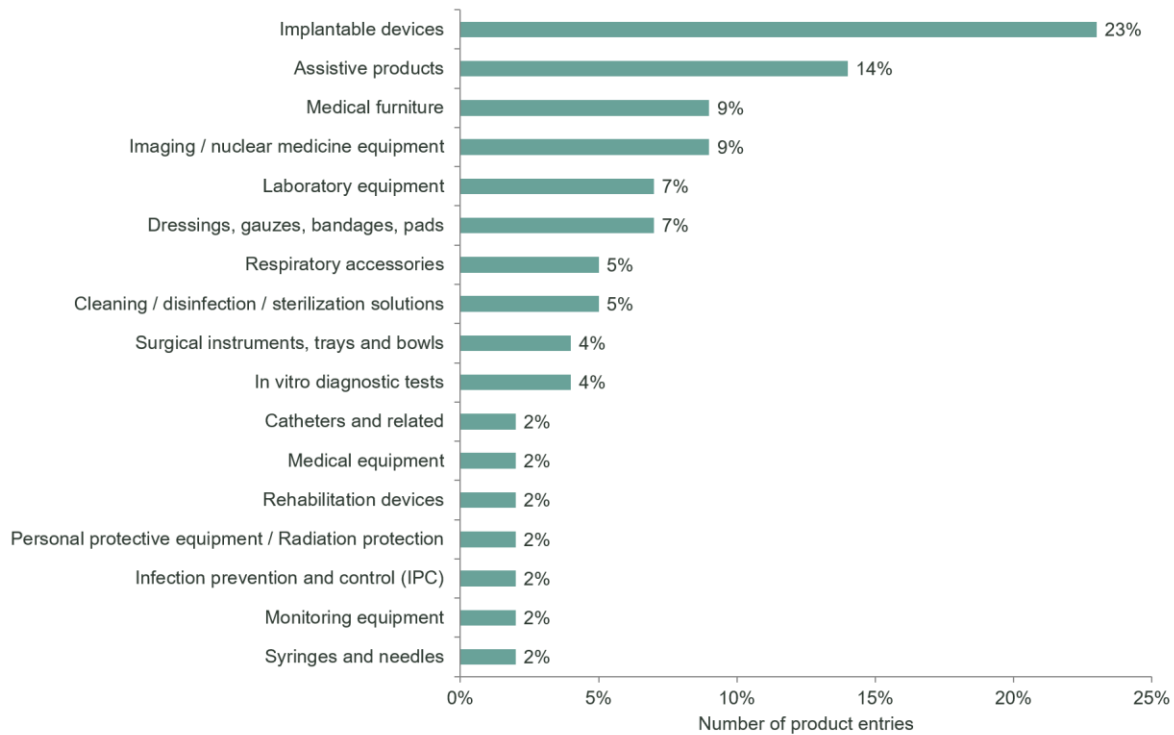


Figure 24: Reported product categories

Customer mix

The pattern splits cleanly along category lines. Implantable devices, imaging equipment, and surgical instruments, the three most clinically complex, highest-value categories, are overwhelmingly private-sector-led (79-88% private). In contrast, laboratory equipment, medical furniture, and assistive products lean towards the public-sector (45-68% public). Notably, in vitro diagnostic tests stand out as the only category where retail/wholesale is the dominant sales channel (64% of sales, versus 26% public and 10% private), the highest retail share of any category in the survey. Both product entries in this category are Rapid Diagnostic Tests (RDTs), a Malaria RDT and a general Rapid Test Kit, which likely explains the pattern (Figure 25).

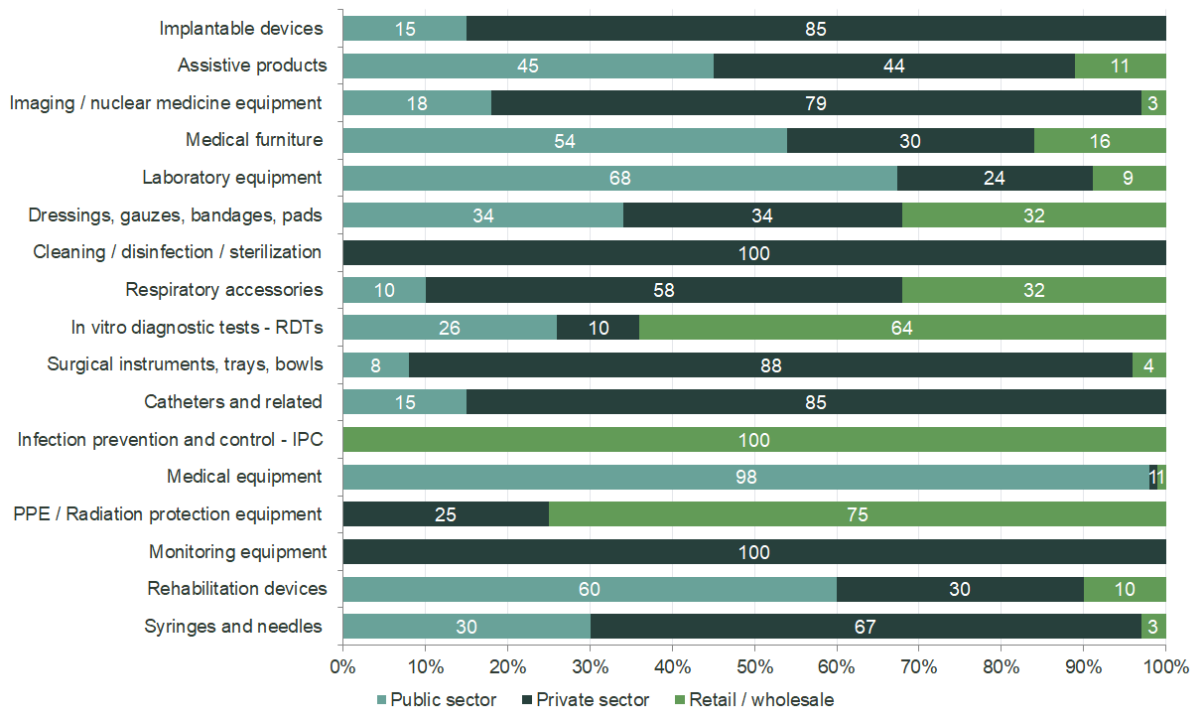


Figure 25: Customer Mix

Dominant Sectors and Markets for Local Supply

As illustrated in the figure below, data collected through the supplier survey indicate that South Africa's public and private healthcare markets remain heavily reliant on imports, with local manufacturers supplying only 29% of the public-sector market and 25% of the private-sector market. The private sector shows marginally deeper import reliance than the public sector, reinforcing that public procurement, where it exists currently, does more to support local supply than private-sector purchasing does. Based on the available survey responses, it is important to note that these results may not be representative of the entire MedTech sector (Figure 26).

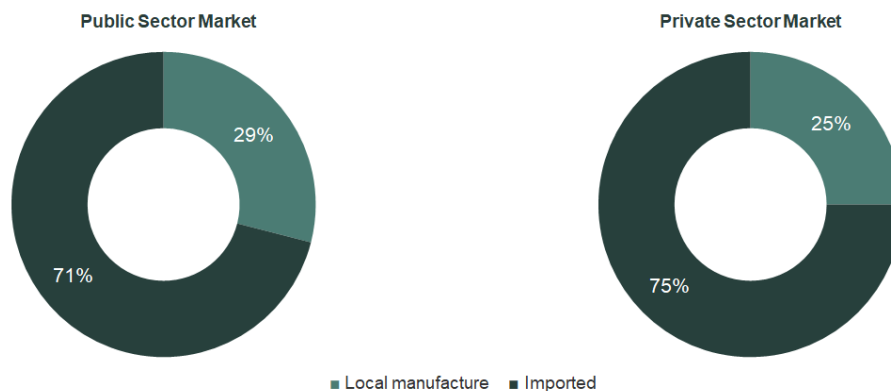


Figure 26: Overall Local Manufactured v/s Import Split

The supplier survey also highlights a high level of import dependence across both public and private healthcare markets, particularly for technologically sophisticated

product categories. Imports account for 90-100% of supply for medical equipment, monitoring equipment, imaging and nuclear medicine equipment, implantable devices, IVDs, IPC products, and PPE, indicating limited local manufacturing capacity in advanced medical technologies. However, import dependence is not uniform across categories. Local manufacturing has gained greater traction in categories where local suppliers capture a meaningful share of the market. Notably, respiratory accessories exhibit the strongest local presence (90-92% locally manufactured), while assistive products, medical furniture and surgical instruments show higher levels of local participation than most other device segments, suggesting relatively stronger local capabilities in rehabilitation, hospital infrastructure and lower-complexity devices (Figure 27).

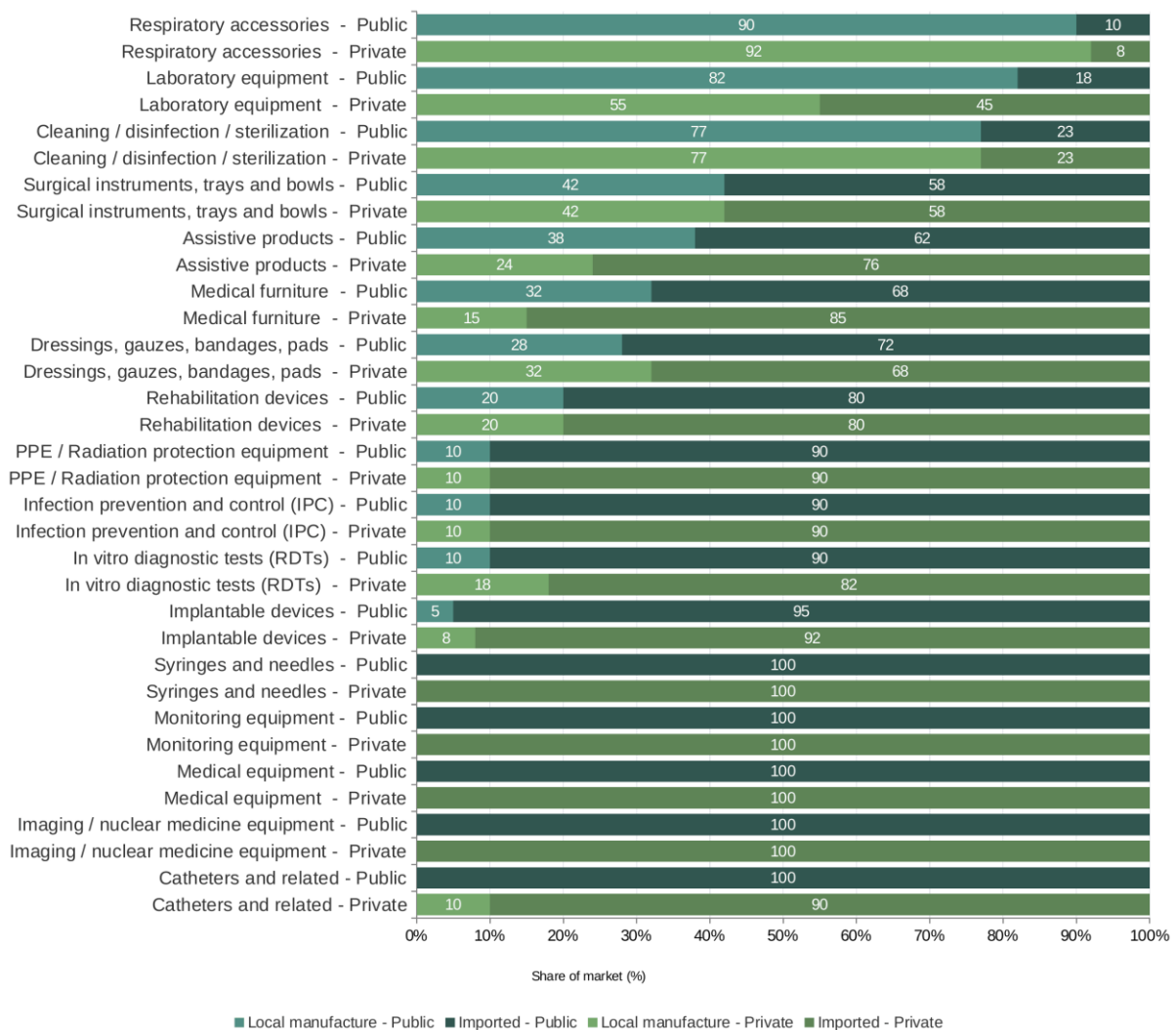


Figure 27: Local Manufacture vs Import Split by Category for Public and Private Users

The findings from the survey also indicate that the South African medical device sector is primarily oriented toward serving the domestic market, with 79% of products supplied within South Africa and 21% exported across all surveyed companies. Even among full local manufacturers, the domestic market remains the primary destination for production, accounting for 71% of supply, while 29% is exported, demonstrating a

stronger export orientation than the overall industry average. At the same time, the fact that nearly three-quarters of locally manufactured products are retained within South Africa highlights the continued importance of the domestic healthcare market as the main driver of production. When viewed alongside the high import dependence observed in many medical device categories, these findings point to a sector where local manufacturing capability exists and is developing export potential but remains concentrated in selected product segments and has yet to significantly reduce reliance on imported advanced medical technologies (Figure 28).



Figure 28: Supply Split: Domestic v/s Exported

The capacity utilisation results from the survey suggest that while a local medical device manufacturing base exists, a substantial proportion of production capacity remains underutilised. Nearly half of the local manufacturers (47%) operate at 51-75% capacity utilisation, indicating some availability for expansion without requiring major new investments. More notably, 47% of manufacturers are operating at 50% capacity or below, including 30% utilising less than a quarter of their installed capacity, pointing to significant idle production capacity across the sector. In contrast, only 7% of manufacturers report utilisation above 75%, suggesting that relatively few firms are approaching production constraints.

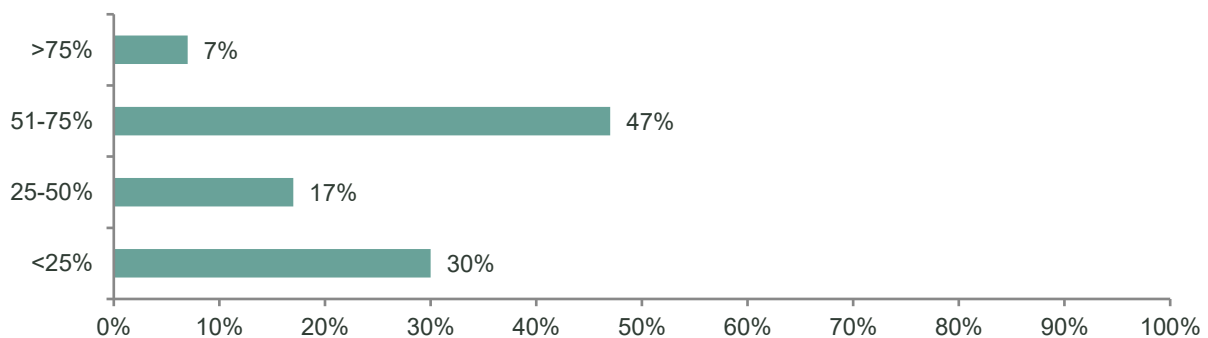


Figure 29: Capacity Utilisation of Local Manufacturers

4.1.2 KEY BARRIERS FOR LOCAL MANUFACTURING

Literature highlights that local firms face significant challenges including high regulatory compliance and certification costs, complex multi-agency approval requirements, limited local testing and accreditation infrastructure, lengthy commercialisation timelines, low levels of R&D investment relative to global benchmarks, fragmented funding mechanisms, and inadequate access to growth capital across the innovation-to-market pipeline. These constraints are further compounded by the SME-dominated nature of the industry, shortages of specialised technical and regulatory skills, weak collaboration between academia, industry and government, delayed public-sector payments, insufficient utilisation of local procurement and industrial policy instruments, limited export support, and strong competition from multinational suppliers that benefit from economies of scale, established international certifications, and established market access approaches.

Collectively, these barriers restrict the commercialisation and scaling of locally developed technologies, constrain investment in local manufacturing, and limit South Africa's ability to reduce import dependence, strengthen healthcare supply security, and develop a globally competitive and resilient medical technology industry. Delayed payments by public-sector healthcare institutions remain a significant constraint on the healthcare ecosystem; for example, provincial debt owed to the NHLS may impact the sustainability of NHLS.

The findings from the supplier survey reinforce and validate the barriers identified across the literature, demonstrating their continued relevance to localisation efforts within the South African MedTech sector.

The survey indicates that the principal barriers to expanding full local medical device manufacturing are high input costs (68%) and regulatory burden (61%), making cost competitiveness and compliance requirements the most significant constraints facing the sector. Secondary challenges include skills gaps (38%) and limited access to finance (36%), highlighting difficulties in securing the specialised talent and investment needed to scale production. In contrast, relatively few respondents identified technology gaps (16%), low demand (16%), or infrastructure limitations (12%) as major obstacles (Figure 30).

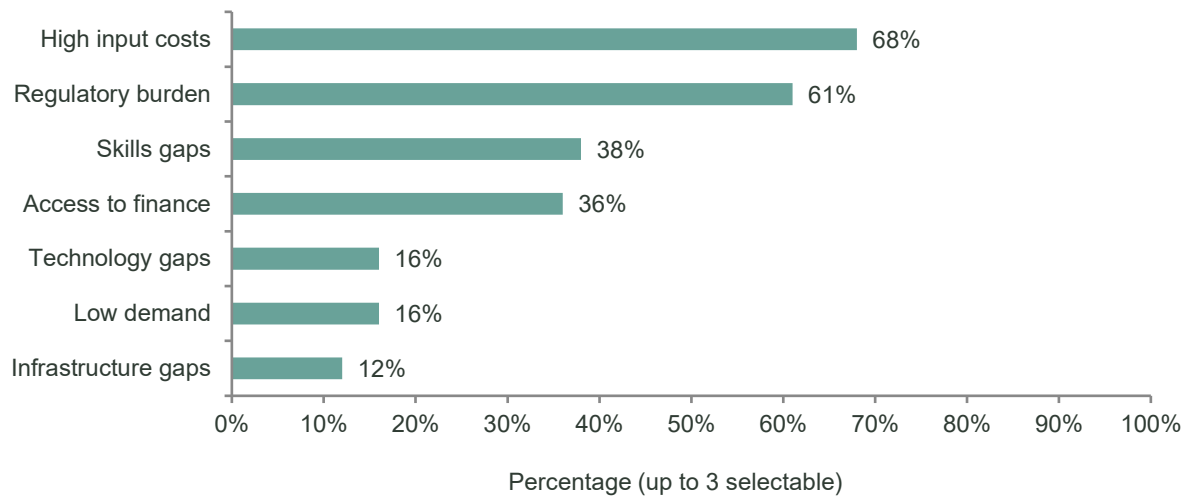


Figure 30: Barriers for Full Local Manufacturing

The analysis highlights that high input costs and regulatory burden are the most significant barriers to localisation across nearly all medical device categories, particularly for high-technology products such as imaging equipment, implantable devices, monitoring equipment, and medical equipment. While these challenges are sector-wide, categories such as assistive products, laboratory equipment, and medical furniture also face notable skills and financing constraints, whereas advanced technologies face additional technology-related barriers. Overall, the findings suggest that the feasibility of local manufacturing is constrained primarily by the cost and regulatory environment, with higher-complexity device categories requiring broader interventions spanning skills development, financing, and technology transfer to support localisation (Figure 31).

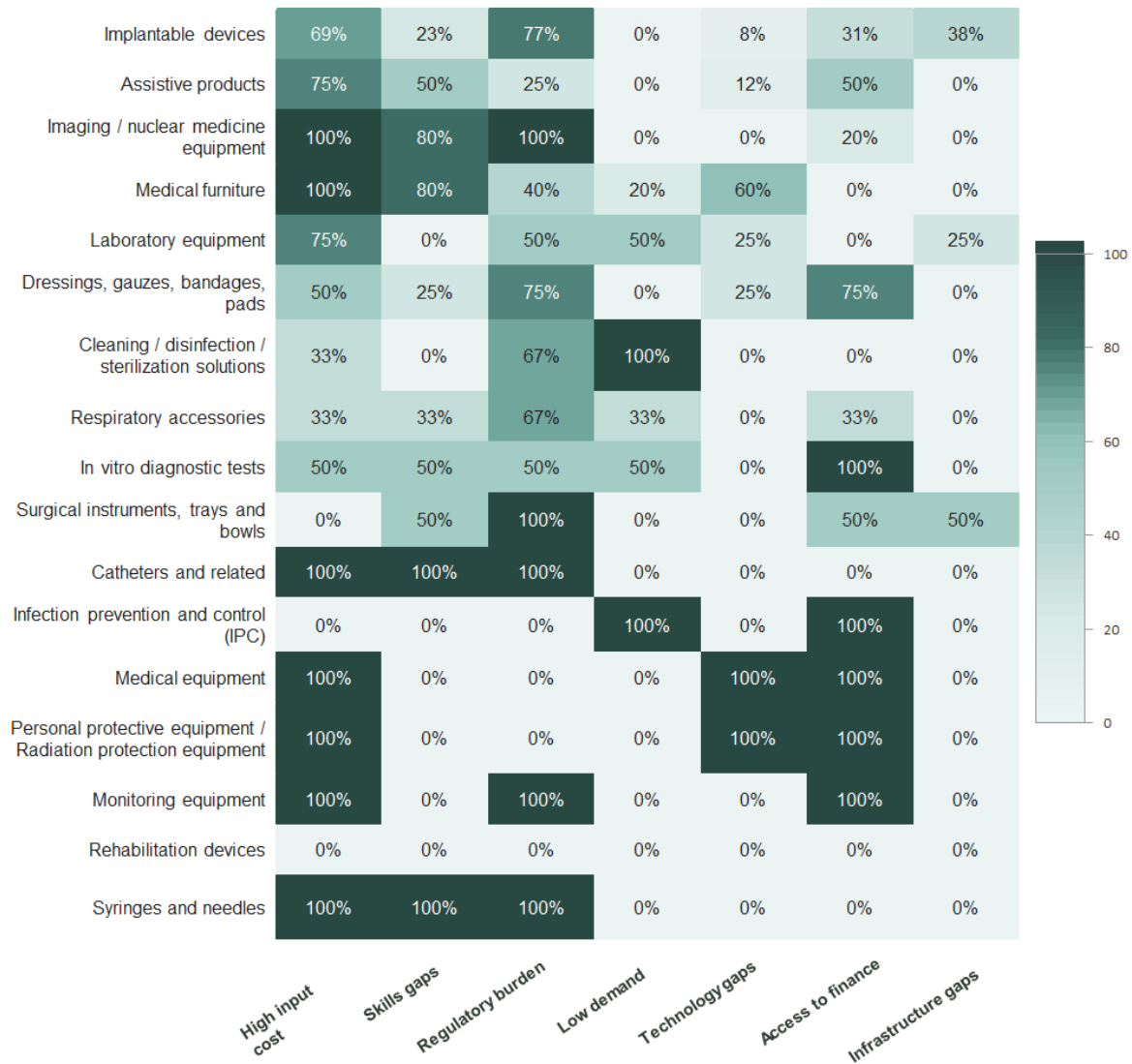


Figure 31: Barrier for Full Local Manufacturing: Category Wise

The findings from the survey also indicate that the public sector is by far the most challenging customer segment for MedTech suppliers, with 63% of respondents identifying it as the toughest market to serve, compared with only 15% for the private sector and 19% reporting no difference across sectors. The primary drivers of these challenges are payment delays (56%) and lengthy procurement and tender processes (44%), highlighting administrative and cash-flow constraints as the most significant barriers to market participation. Commercial pressures also remain important, with pricing pressures and low margins (37%) cited frequently, while limited access to buyers and procurement systems (26%), demand uncertainty (22%), and strong competition (22%) further complicate supplier engagement. In contrast, relatively few suppliers identified regulatory requirements, distribution constraints, or technical product requirements as major obstacles (Figure 32).

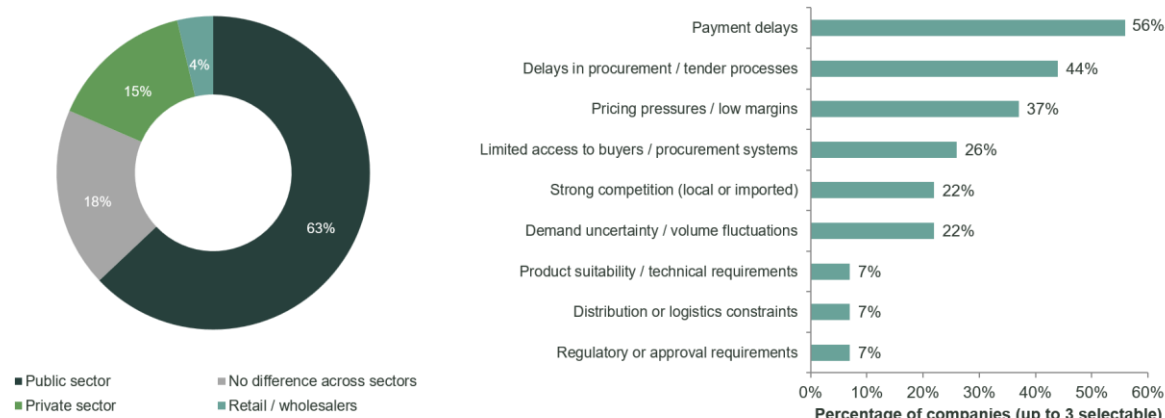


Figure 32: Challenges in Serving Public Sector

Similar findings have been noted from stakeholder consultations. These barriers and constraints have been summarised below:

Table 4: Key Barriers to Localisation

MARKET CONSTRAINTS		STAKEHOLDER GROUPS HIGHLIGHTING THE BARRIER
Fragmented demand	Public sector demand is dispersed across national, provincial, and facility level procurement systems, with limited demand aggregation or long-term visibility.	National and provincial government representatives; Industry associations; Academia; Suppliers;
Procurement Structures	Evidence from the stakeholder consultations indicates that public tenders are predominantly price-weighted (often 80-90% of evaluation criteria), with limited formal consideration of supply reliability, local value addition, or long-term industrial outcomes. Contract durations are typically short, limiting demand visibility and reducing incentives for manufacturers to invest in capital equipment, tooling, or workforce expansion. Payment performance further undermines supplier participation. Stakeholders reported payment arrears exceeding R10 billion across the public health sector, creating severe cashflow pressure for suppliers, particularly SMEs that lack access to low-cost working capital. These conditions increase the effective	National and provincial government representatives; Industry associations; Suppliers; Academia; Private sector buyers

	cost of doing business locally and favour import-based distribution models with stronger balance sheet backing. Stakeholders also indicated that in the private sector, purchasing decisions are concentrated among a small number of hospital groups and medical schemes, which tend to favour established multinational suppliers with bundled service offerings and proven track records.	
Supply-side constraints		
Skills	Stakeholders consistently cite shortages of specialised engineers, toolmakers, regulatory professionals, and quality assurance experts as a binding constraint on advanced manufacturing. While South Africa possesses pockets of excellence, skills pipelines are uneven, and firms outside established industrial hubs face additional challenges in attracting and retaining qualified personnel. This constrains the sector's ability to move beyond basic manufacturing into higher-value activities.	Suppliers; Industry associations; National and provincial government representatives; Academia
Infrastructure	Infrastructure constraints compound skills shortages. Advanced manufacturing requires reliable utilities, cleanroom environments, and precision equipment, which are unevenly distributed across regions. As a result, manufacturing activity is concentrated in a small number of industrial hubs, limiting broader geographic participation in localisation efforts.	Suppliers; Regulators; Academia; Industry associations; National and provincial government representatives
Market Intelligence	A further structural barrier is the absence of integrated market intelligence. There is no centralised database capturing device level procurement, utilisation, or pricing across public and private sectors. Stakeholders estimated that industry bodies receive responses from only 5-10% of suppliers when attempting to map local manufacturing activity, severely limiting visibility into actual supply capability.	National and provincial government representatives; Industry associations; Academia; Suppliers;

Finance and Regulatory Constraints		
Compliance Costs	Certification and regulatory compliance costs represent another significant barrier. While South Africa's regulatory framework is aligned with international best practice, the fixed costs associated with quality management systems, conformity assessments, clinical evidence generation, and post market surveillance weigh disproportionately on smaller firms. The absence of locally accredited testing and certification facilities for certain device categories forces manufacturers to rely on offshore laboratories, increasing both cost and time to market. These constraints are particularly acute for higher risk devices, even where technical production capability may exist.	Suppliers; Industry associations; National and provincial government representatives; Regulators; Academia;
Access to capital	Access to capital remains limited. MedTech manufacturing typically requires upfront investment with long payback periods, particularly where regulatory approval timelines are complex and require offshore reviews. Local firms report difficulty accessing financing instruments that align with these characteristics, resulting in under-investment, delayed expansion, or reliance on import-based business models with lower risk profiles. Without appropriate financial instruments, even firms with demonstrated capability struggle to scale production or enter new categories.	Suppliers; Industry associations; Academia; National and provincial government representatives

4.1.3 KEY ENABLERS FOR LOCAL MANUFACTURING

The findings from the supplier survey indicate that stakeholders view quality assurance and production readiness support as the most critical enablers of localisation and strengthening it. Testing and certification support (57%) emerged as the top priority, followed by CAPEX support for equipment and cleanrooms (48%) and funding for quality systems (48%), underscoring the importance of meeting regulatory and quality requirements for medical device manufacturing. Secondary needs include skills development (27%), reduced import duties on raw materials (25%), and procurement support (23%), reflecting ongoing challenges related to workforce capability, input costs, and market access. In contrast, technology transfer (16%) and access to finance (16%) were cited less frequently (Figure 33).

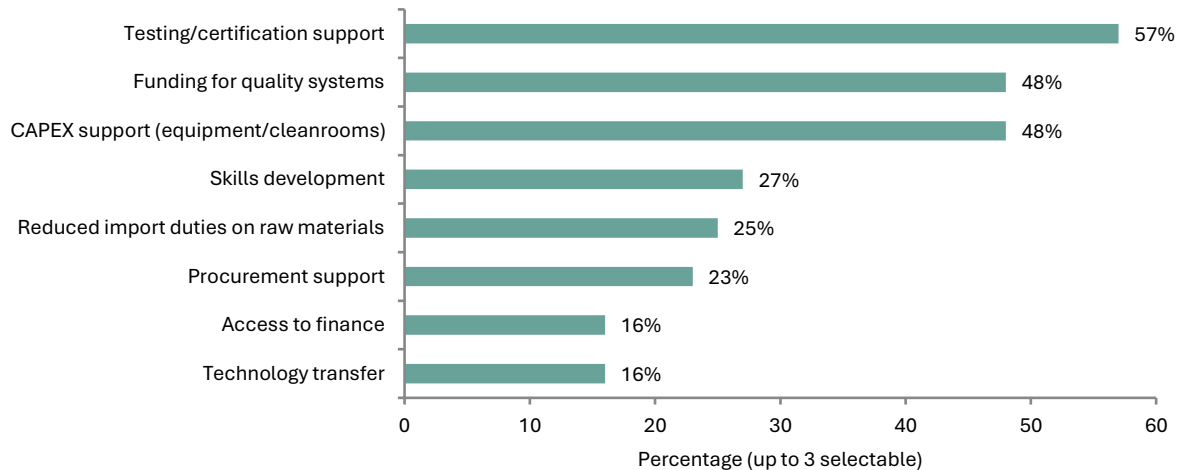


Figure 33: Enablers for Local Manufacturing

The enabling factors identified in Tables 5-9 below were raised across multiple stakeholder groups, including national and provincial government representatives, suppliers, regulators, academia, buyers, and industry associations. Responsive manufacturing during COVID-19 and the experiences of export-oriented local manufacturers further demonstrated that localisation could succeed where procurement certainty, regulatory support, and market access mechanisms are aligned.

Responsive Manufacturing During Supply Disruptions

Periods of acute supply disruption, most notably during the COVID-19 pandemic, provided a stress test for South Africa's MedTech supply base and revealed latent local manufacturing capability. When global supply chains failed, local firms were able to respond rapidly once three enabling conditions aligned: clear articulation of demand, temporary regulatory flexibility, and access to bridging finance (Table 5).

Local manufacturers repurposed existing facilities and scaled production of PPE, sanitisation products, and selected diagnostic components. While much of this activity was emergency driven, it demonstrated that manufacturing capacity exists but is normally dormant due to weak demand certainty and high regulatory friction.

Table 5: Characteristics of Responsive Manufacturing Episodes

Enabling Condition	Observed Effect
Clear demand signals	Rapid mobilisation of production capacity
Expedited regulatory pathways	Reduced time to market
Bridging or emergency finance	Short-term scale-up feasible
Time-bound procurement commitments	Reduced supplier risk

Importantly, some firms retained elements of this capacity post-crisis, redirecting output toward regional export markets or adjacent product lines, suggesting that emergency driven localisation can generate durable industrial capability if followed by market stabilisation.

Sub-National Procurement Initiatives as Localisation Enablers

Stakeholder consultation also highlighted that sub-national procurement models are an important enabler of local supplier participation, even where explicit localisation mandates are absent. The Western Cape Provincial Procurement Model is cited as an example of more professionalised purchasing that has indirectly supported local manufacturers.

Key features of this model include the use of commodity specialists, clearer technical specifications, and multi-year contracting frameworks, which improve predictability and reduce transaction costs for suppliers. (Table 6)

Table 6: Procurement Design Features Supporting Local Participation

Feature	Effect on Suppliers
Multi-year contracts	Improves investment planning
Clear specifications	Reduces compliance uncertainty
Professionalised procurement	Lowers transaction costs
Volume signalling	Enables scale planning

These examples suggest that **procurement reform is a localisation lever**, not because it mandates local sourcing, but because it improves the underlying economics of local participation.

Hybrid Supply Models and Incremental Value Chain Deepening

Evidence also highlights emergence of hybrid supply models, in which imported components are combined with local assembly, packaging, kitting, or final stage processing. These models have been observed in diagnostic kits, consumables, and selected equipment categories.

Such arrangements allow local firms to participate meaningfully in value chains while avoiding the high capital intensity and regulatory burden associated with full upstream manufacturing. (Table 7).

Table 7: Characteristics and Benefits of Hybrid Supply Models

Dimension	Hybrid Model Advantage
Capital intensity	Lower than full manufacturing
Regulatory burden	More manageable
Lead times	Shorter than full imports
FX exposure	Reduced
Skills development	Progressive

These models are particularly well-suited to categories where full localisation is not immediately viable, but where incremental local participation can still deliver economic and supply chain benefits.

Existing Local Champions and Export Competitive Niches

The reports identify a limited number of local manufacturing “champions” and export competitive niches that demonstrate what is achievable under the right conditions.

Trade data show that some categories recorded paired growth in local manufacturing and exports between 2021 and 2025.

Examples include fixation devices, blood grouping reagents, ophthalmic instruments, and selected imaging related systems. While these categories represent a small share of total market value, they provide proof of concept for world class MedTech manufacturing in South Africa (Table 8).

Table 8: Characteristics of Export Competitive Local Niches

Characteristic	Common Feature
Product focus	Narrow, specialised
Quality systems	Early investment
Market orientation	Export linked
Regulatory engagement	Proactive
Scale strategy	Niche, not mass

These cases underscore that localisation success is category-specific and should be scaled selectively rather than generalised across the market.

Collaborative Approaches to Skills and Certification Gaps

Another enabling factor identified is the emergence of collaborative approaches between industry, regulators, and training institutions to address skills shortages and certification bottlenecks.

Examples include early engagement with regulators to clarify requirements, shared training initiatives on quality management systems, and joint problem-solving around certification timelines. While these initiatives do not lower regulatory standards, they improve predictability and efficiency, reducing avoidable delays (Table 9).

Table 9: Collaborative Enablers Addressing Systemic Constraints

Constraint	Collaborative Response
Regulatory uncertainty	Early regulator-industry dialogue
Skills shortages	Shared training initiatives
Certification delays	Pre-submission engagement
SME entry barriers	Pooled advisory support

Despite the structural constraints facing localisation in South Africa's MedTech sector, the evidence identifies a number of enablers and emerging practices that demonstrate the feasibility of expanded local participation under appropriate conditions. These examples show that localisation outcomes improve when demand signals are clear, institutional coordination is strengthened, and regulatory and capability constraints are addressed in a proportionate manner. Taken together, they indicate that localisation need not compromise quality, cost control, or system performance, provided interventions are targeted, incremental, and aligned to market realities (Figure 34).

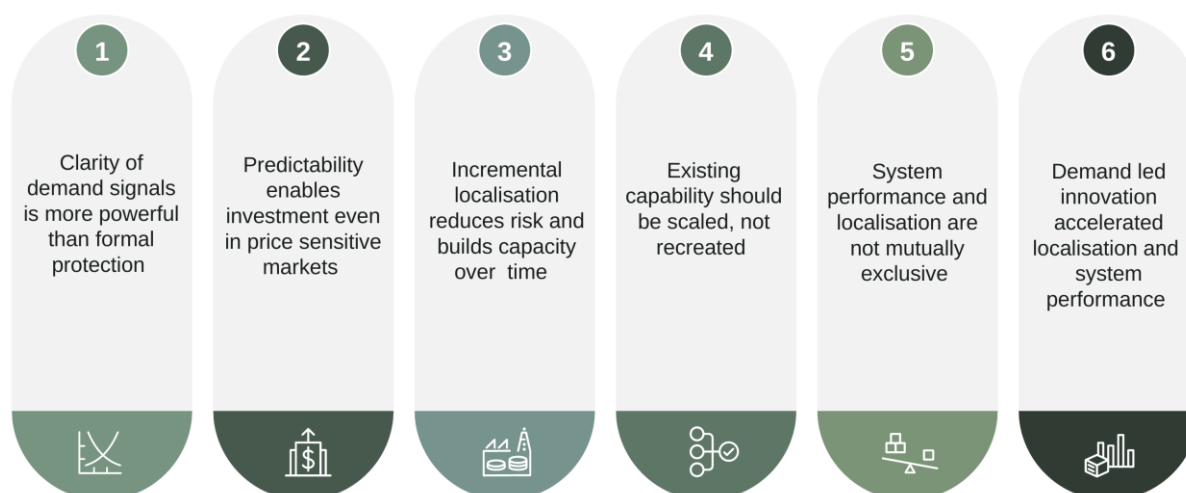


Figure 34: Key Enablers for Localisation

Triangulation with literature also highlights several critical enablers that include:

- A dedicated Medical Technology Industrialisation Programme to coordinate localisation, manufacturing, innovation, procurement, financing and export development across the sector.
- Strategic use of public procurement as a market-shaping instrument, including product-specific localisation targets and preferential procurement for locally manufactured medical devices where competitive local capability exists.
- Longer-term government procurement contracts to create predictable demand and encourage investment in local manufacturing capacity.
- A differentiated procurement framework that recognises differences between product categories and allows enhanced localisation weighting for selected medical technologies.
- An efficient, adequately resourced and enabling regulatory environment, including strengthened regulatory agencies, reduced compliance burdens and accelerated approval pathways for locally developed technologies.
- Dedicated commercialisation and manufacturing finance mechanisms, supported by faster funding approval processes and simplified access to industrial finance.
- Medical technology manufacturing hubs and Special Economic Zone (SEZ)-based clusters providing shared access to testing, certification, sterilisation, prototyping and manufacturing infrastructure.
- Increased support for SMEs, start-ups and innovators through business development support, mentorship programmes, commercialisation assistance and technical support services.

- Sector-specific skills development programmes focused on biomedical engineering, regulatory affairs, diagnostics, quality assurance and advanced manufacturing.
- Stronger collaboration between government, industry, academia and research institutions to support innovation, technology transfer and workforce development.
- Expanded regional market integration through AfCFTA and regional economic communities such as SADC to increase export opportunities, harmonise standards and create larger markets for locally manufactured medical technologies.
- Attraction of multinational medical technology manufacturers through targeted investment incentives, technology transfer programmes and a supportive investment environment.
- Localisation support measures linked to measurable outcomes such as local content, employment creation, investment, technology transfer and export growth.
- Improved government payment performance and reduced payment delays to healthcare suppliers to strengthen business sustainability and investor confidence.
- Development of regional value chains and export-oriented manufacturing strategies to improve economies of scale and reduce dependence on the domestic market.
- Evaluation of industrial incentives based on their broader developmental impact, including job creation, manufacturing expansion, innovation outcomes and fiscal returns, rather than solely on firm-level profitability.
- The Registration Feasibility Study highlights regulatory system strengthening as a key enabler of medical device localisation. Recommended interventions include a phased risk-based registration framework, reliance-based regulatory pathways, strengthened stakeholder engagement, digital regulatory infrastructure, enhanced regulatory capacity, support for local manufacturers in conformity assessment, and alignment with international standards. These measures aim to improve regulatory efficiency, facilitate market access, strengthen investor confidence and support the development of a competitive local medical device sector.

4.2 Localisation Pathways

The localisation pathway analysis suggests that the greatest opportunities for strengthening local manufacturing lie in product categories where respondents

identified full local manufacturing as the most viable route to localisation. This is particularly evident for dressings, gauzes, bandages and pads, respiratory accessories, IPC products, PPE/radiation protection equipment, rehabilitation devices, and assistive products, where local manufacturing is viewed as the dominant or exclusive pathway. These categories typically involve lower-to-medium technology complexity and align with areas where local manufacturers already demonstrate some market presence.

In contrast, categories such as implantable devices, laboratory equipment, surgical instruments, and imaging equipment show a more fragmented localisation outlook, with respondents identifying a mix of local manufacturing, distribution, import local manufacturing (own brand), and label manufacturing as viable approaches. Notably, implantable devices, despite being one of the most import-dependent categories, received support across multiple localisation pathways, indicating potential for gradual localisation but also reflecting the technical and regulatory challenges associated with local manufacturing. The findings also highlight important constraints for certain product groups. Imaging and nuclear medicine equipment is dominated by label manufacturing (60%) and distribution (40%), with no respondents identifying full local manufacturing as a realistic pathway (Figure 35).

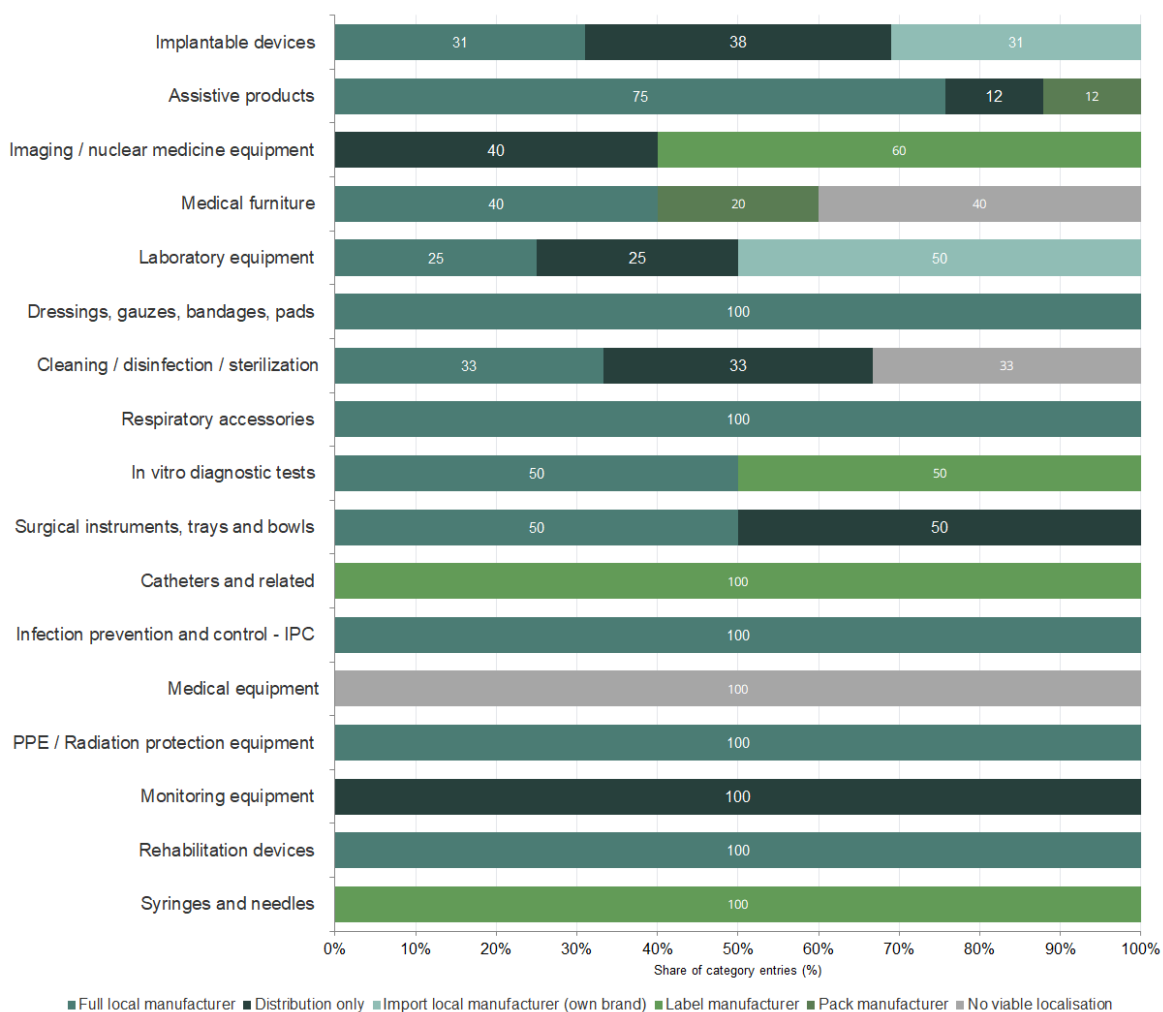


Figure 35: Localisation Pathway

The findings suggest a moderate but not universal appetite for moving up the medical device value chain among non-full-local manufacturers. Of the non-full-local-manufacturer product entries assessed, 43% indicated a willingness to progress to a higher-value localisation model, while the majority (57%) reported no intention for upward movement. Among those seeking to upgrade, the most common pathway is label manufacturing (58%), followed by full local manufacturing (33%), with only 8% aiming to transition to an import local manufacturing (own brand) model. See Figure 36 below.

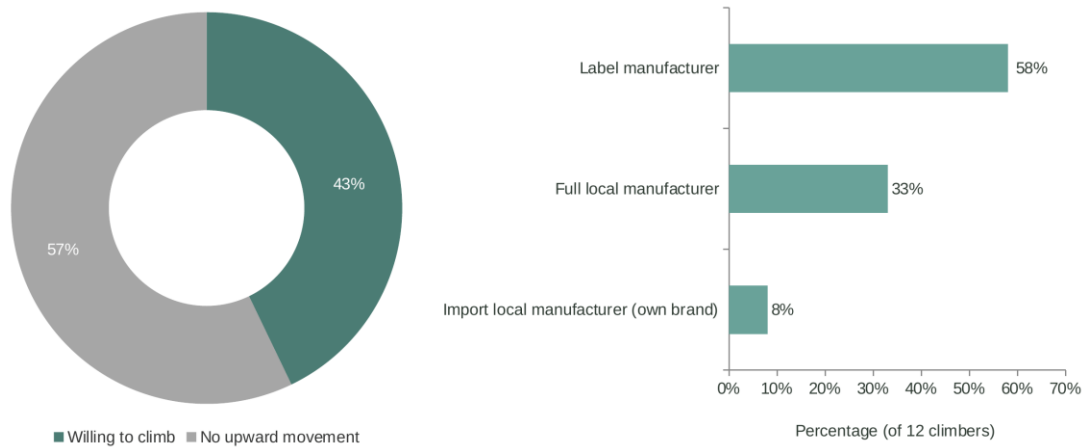


Figure 36: Appetite for Moving Up in Value Chain

4.3 Devices for Localisation

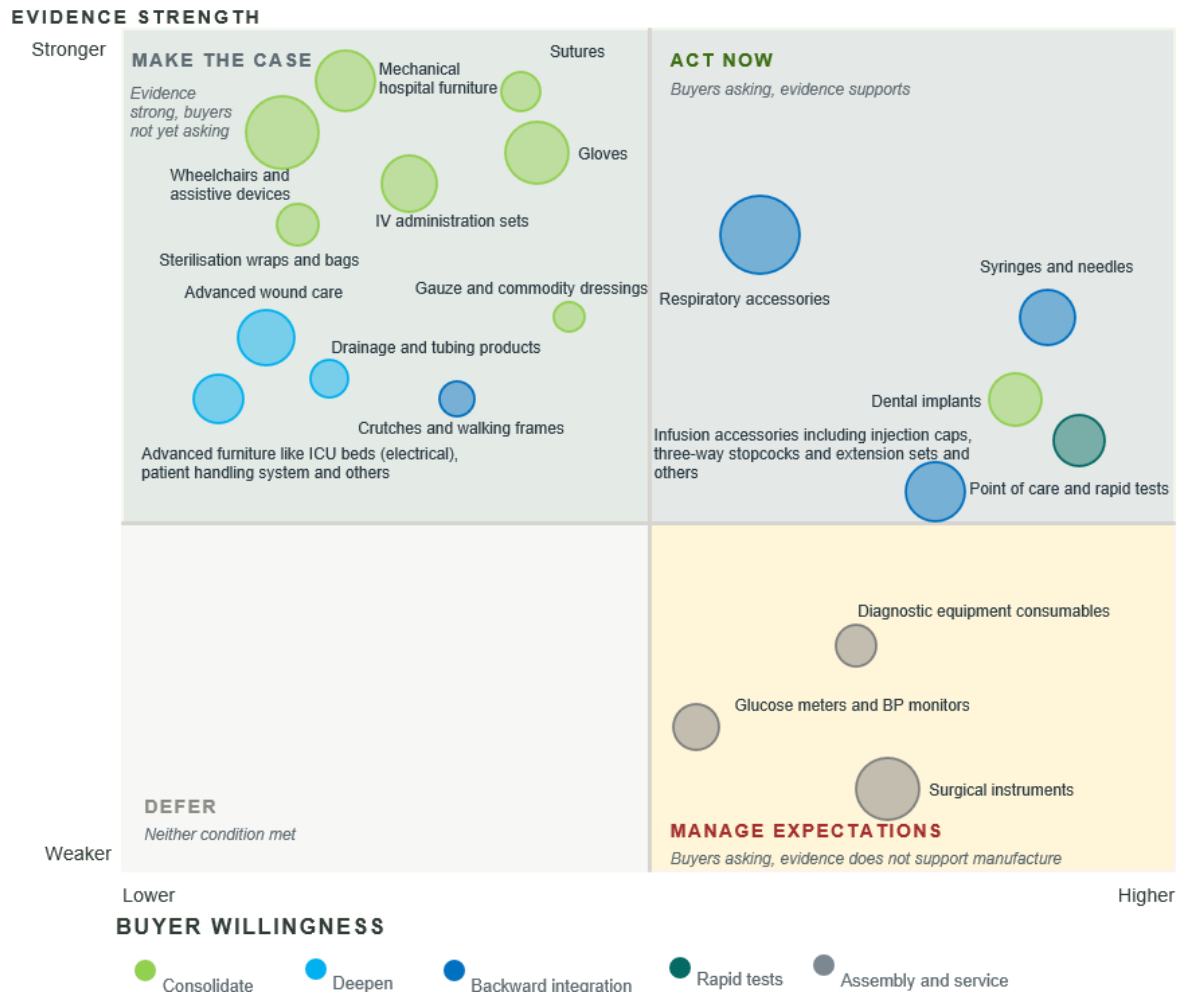


Figure 37: Potential Devices for Localisation

The product categories presented in Figure 37 were identified through triangulation of multiple data sources, including key informant interviews (KIIs), the supplier survey, import data from SARS, demand estimation data from LOGIS and BAS, National Treasury transversal contracts and NHLS annual reports. These sources were combined to assess both buyer demand and localisation potential across different medical device categories. The resulting prioritisation framework reflects the convergence of stakeholder perspectives, procurement patterns, market demand signals, and available evidence on local manufacturing capability.

Consolidate and Scale Established South African Manufacturing Capability

Risk profile: predominantly Class A, with Class B and limited Class C exposure.

Categories already contain local manufacturers operating at commercial scale and competing directly against imported products on identical specifications. These require demand certainty rather than new capacity, technology transfer or regulatory capability building. Manufacturers in these categories already hold the necessary establishment licences and quality management systems.

Strategic recommendations

- **Sutures** should be prioritised for immediate coordinated state procurement. Evidence confirms that the majority of contracted products are manufactured locally, in a category that is growing rapidly annually. This is the highest risk class in which meaningful local manufacturing is currently established, and it demonstrates that South African manufacturers can satisfy Class C requirements where commercial conditions justify the investment. **Support should extend capability into the specialised and premium ranges presently supplied by international manufacturers.**
- **Wheelchairs and other assistive and rehabilitative devices**, which fall predominantly within Class A, should be maintained and extended. The category is already predominantly locally manufactured or assembled, with the leading local suppliers accounting for a large share of procurement. **Intervention should target specialised powered mobility devices, complex seating systems, paediatric rehabilitation products, pressure-relief systems, and customised assistive technologies.**
- **Surgical and examination gloves** require intervention directed at **supply reliability**, increasing manufacturing capacity and reliable demand. Local manufacturers supply the overwhelming majority of the range, but quote longer supply lead times than the leading importer. Working capital support for finished goods stockholding is the appropriate instrument. Scaling manufacturing capacity to optimum levels will support import substitution of these devices.
- **Sterilisation consumables (wrap and bag) and mechanically operated hospital furniture**, both predominantly Class A, **should be prioritised for coordinated state procurement.** Local furniture product is cheaper than the imported equivalent in the majority of directly comparable items and is delivered more quickly. This is the only category examined in which local manufacture competes on cost, and there is no economic or regulatory justification for continued importation of standard ward furniture.
- **Intravenous administration sets and infusion consumables** should be prioritised as a capability protection and expansion opportunity. This segment already has an established manufacturing base producing standard administration sets, blood administration sets, paediatric sets and burette sets. However, local

participation has faced stiff competition from imports. Given the existing manufacturing capability, regulatory readiness and demonstrated procurement demand, intervention should focus on defending and scaling existing production through meaningful coordinated state procurement, revised tender weighting and long-term volume commitments.

Deepen Manufacturing in Partially Localised Categories

Transition from Class A to Class B and C within the same category.

Categories exhibit a consistent structure in which local manufacturing holds the technically simpler and lower risk-class segment, while the larger or higher-value segment, typically one risk class higher, remains imported. The capability gap is incremental, but in several instances the regulatory gap is not, and this distinction should govern the sequencing and the choice of instrument.

Strategic recommendations

- **Advanced wound care** represents a genuine risk-class transition and must be treated as such. Commodity gauze, cotton and paraffin products, falling within Class A, are already predominantly locally sourced. Silver, alginate, hydrocolloid, hydrofiber, foam, collagen and negative-pressure technologies, which carry an ancillary medicinal or pharmacological action, attract a materially higher classification and correspondingly greater clinical evidence and registration requirements. Existing local converters hold the manufacturing base but not necessarily the regulatory capability, and support should therefore combine technology licensing with regulatory affairs capacity building.
- **Drainage and tubing products** within collection devices, falling within Class B, should be scaled from the established local base. Ostomy and urostomy products, representing the major share of category expenditure, should be explicitly excluded from near-term targets, as substitution is constrained by proprietary adhesive and barrier technologies rather than by regulatory burden alone.
- **Medical furniture** presents another category where localisation has already achieved considerable success. Local capability is particularly strong in fabricated steel furniture products such as trolleys, overbed tables, bedside lockers, examination couches, ward furniture, and manually operated hospital beds. Establish local manufacturing capacity particularly for **electrically actuated ICU beds, advanced examination couches, and electronically controlled patient handling systems.**

Support Backward Integration by Established Importers

Predominantly Class A and B.

Several categories are supplied almost entirely by South African registered companies importing finished product under their own or licensed house brands. These firms already hold regulatory registration as importers and distributors, together with brand recognition, distribution infrastructure and public sector market access. The transition

from importer to manufacturer requires an upgrade of establishment licensing and quality management systems rather than their creation, which materially reduces the regulatory barrier relative to a new entrant. The categories identified sit within the lower risk classes, making this transition achievable.

Strategic recommendation

- **Respiratory accessories** represent the clearest and most urgent case. The category is growing rapidly, expenditure is concentrated in ventilator breathing and other circuits and masks, with few suppliers accounting for a major share of the spend. These are bulky, low value-density products manufactured through extrusion, moulding and manual assembly, falling within the lower risk classes as accessories rather than as active devices.
- **Syringes and needles**, falling within Class B, should be approached selectively rather than as a category. Plain two-part and three-part syringes supplied without needles are injection-moulded products requiring no specialised materials or precision metalwork and are fully localisable.
- **Crutches, walkers and walking frames**, falling within Class A, are sourced predominantly from China and Taiwan through local distributors. These are tubular metal fabrications well within existing engineering capability and carry the lowest regulatory burden of any category examined.
- **Infusion accessories and moulded components**, including **injection caps, three-way stopcocks and extension sets**, should be prioritised for backward integration. These products share common manufacturing processes, materials and interfaces with administration sets already produced locally, suggesting that the primary constraint is production scale and unit cost rather than technical capability. Localisation efforts should therefore aggregate demand across the broader infusion consumables basket to create sufficient manufacturing volumes and enable local manufacturers to compete more effectively with imported commodity components.

Pursue Assembly, Service and Refurbishment Localisation in Advanced Technology Categories

Class C and Class D.

Many categories are not realistic candidates for local manufacturing within the medium term, and in each case regulatory risk classification is a primary rather than incidental barrier. Medical equipment, imaging and endoscopy platforms fall predominantly within Class C. Implantable devices span Class C for orthopaedic and trauma fixation and intraocular lenses, and Class D for cochlear implants, cardiovascular stents, vascular grafts and allograft tissue products. Class D devices attract the most stringent conformity assessment, the most extensive clinical evidence requirements and the longest registration pathways, and are additionally protected by proprietary technology, instrument loan set ecosystems and established surgeon familiarity. In these categories, import dependence is tied to regulatory position and technological

capability rather than to cost structure, and localisation policy directed at manufacture will not succeed.

Strategic recommendations

- **Service and maintenance capability** should be the principal focus. Each item contracted under the medical equipment transversal contract carries a two-year warranty and a five-year post-warranty comprehensive maintenance schedule, binding the purchaser to the original manufacturer for a seven-year lifecycle. This constitutes the largest realistically capturable value pool in these categories, and it carries a materially lower regulatory burden than manufacture, since servicing and maintenance do not require product registration. It should be addressed through certified in-country service partnerships, mandatory skills transfer conditions in equipment contracts, and investment in public sector biomedical and clinical engineering capacity.
- **Final assembly, calibration, installation and configuration** of imported subsystems should be encouraged as a route to partial local content that does not transfer full manufacturer liability or trigger the complete registration pathway applicable to an original manufacturer.
- **Refurbishment and replacement parts supply** should be developed as a distinct industrial opportunity. The recurring aftermarket streams indicate a substantial serviceable market presently supplied entirely from abroad, much of it comprising components which do not independently attract high-risk classification. However, refurbishment activities must be undertaken within an appropriate regulatory framework to ensure product safety, performance, traceability, and compliance with SAHPRA requirements. Particular attention should be given to defining which devices and components are suitable for refurbishment, the quality management and validation requirements applicable to refurbished products, and the responsibilities of manufacturers, service providers, and healthcare facilities.

Establish Rapid Diagnostic Test Manufacture as the Sole Viable In Vitro Diagnostics Opportunity

- **Local rapid diagnostic test manufacture** should be established or scaled in sequence by regulatory risk class rather than by volume. **Lower-class tests, including pregnancy and fertility tests and urinalysis strips**, carry the least onerous registration pathway and should be targeted first to build quality management system maturity and regulatory track record. **Malaria rapid diagnostic tests** should follow as the primary near-term objective. Local capability already exists, the disease burden is regional, and the product supports both national programme requirements and an export market across Southern and Eastern Africa that no local competitor presently serves at scale. **High-burden infectious disease tests, most significantly for HIV**, should be treated as a later phase. These attract the highest in vitro diagnostic risk classification.

- **Antibody and antigen supply** requires explicit attention. The biological input is the highest-value component of a rapid diagnostic test and is almost entirely imported. Local manufacture without a secured antibody supply arrangement replicates the dependency it seeks to resolve, at a lower point in the value chain. Partnership with national academic and research institutions holding relevant immunology capability should form part of any support package.

Accessories and Consumables - A cross-cutting theme

- **Respiratory accessories should be treated as the highest-priority accessory opportunity** in the entire procurement basket, on the strength of expenditure scale, growth rate, standardised interfaces, favourable freight economics and low regulatory classification. The analysis identifies respiratory circuits and masks, suction and drainage tubing, sterilisation packaging, bed mattresses and covers, general surgical consumables and mobility aid accessories as viable, while excluding diagnostic reagents, endoscopy components, actuator assemblies and platform-specific sterilisation consumables.
- **Infusion consumables should be recognised as a strategic accessory localisation opportunity. Administration sets, blood sets, extension sets, injection caps and stopcocks are characterised by standardised interfaces, low regulatory complexity, established local capability and favourable manufacturing economics.** These products align closely with other priority accessory categories such as respiratory circuits, masks, drainage tubing and sterilisation packaging. In contrast, **specialised vascular access technologies such as intraosseous access** devices remain better suited to advanced technology localisation pathways due to higher complexity and the absence of existing local manufacturing capability.

4.4 Policy and Market Recommendations

The analysis of South Africa's MedTech market highlights a set of structural constraints that limit local participation despite sustained demand growth and demonstrated capability in selected segments. These constraints are systemic rather than firm-specific and require coordinated policy and market responses that operate across procurement, regulation, skills development, data governance, and private sector engagement.

The policy and market options outlined below are intended to address identified constraints in a proportionate and phased manner. They are presented as complementary pathways, rather than standalone solutions, and should be assessed and implemented within prevailing fiscal, regulatory, and institutional frameworks. Importantly, the recommendations emphasise sequencing and piloting, recognising

that localisation outcomes are most sustainable when interventions are tested, refined, and scaled based on observed performance (Figure 38).

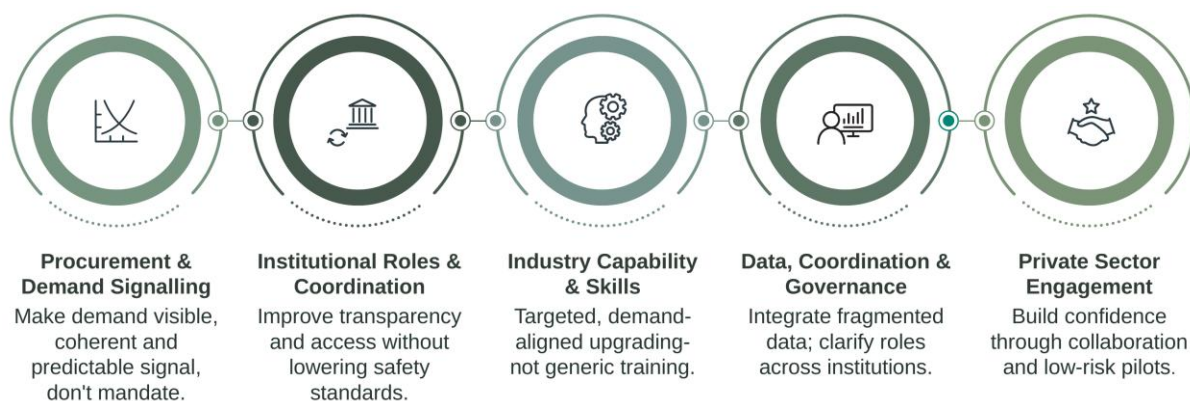


Figure 38: Policy and Market Recommendations

1. Procurement and Demand Signalling

Procurement design and demand signalling emerged as a **central determinant of localisation feasibility**. While South Africa's public sector represents the largest source of MedTech demand by volume, fragmented purchasing structures and limited demand predictability undermine the ability of local manufacturers to invest and scale.

- **Strengthen Demand Aggregation and Forecasting**

A primary policy lever lies in **improving the visibility, coherence, and predictability of demand**. This does not require fundamental restructuring of procurement systems, but rather targeted adjustments that allow suppliers to better understand expected volumes, specifications, and time horizons.

Improved demand aggregation, whether across provinces, facilities, or programmes, can reduce uncertainty and enable manufacturers to plan production more efficiently. Similarly, structured demand forecasting based on historical utilisation and programme projections can provide a credible basis for investment decisions, even where procurement remains decentralised.

Such approaches are particularly relevant for **high-volume consumables and basic diagnostic products**, where aggregate national demand is substantial but currently fragmented across multiple purchasing entities.

- **Consider Contract Structures That Balance Flexibility and Planning Horizons**

The analysis indicates that **short-term, price-focused contracts** limit localisation incentives by constraining planning horizons. While flexibility remains important, particularly in dynamic clinical environments, there is scope to explore **contract structures that balance flexibility with longer-term visibility, such as framework agreements or multi-year contracts with periodic review points**.

Longer planning horizons can reduce supplier risk, support capital investment, and lower unit costs over time, without locking purchasers into inflexible arrangements. Importantly, these mechanisms can be applied selectively to priority product categories where localisation feasibility is strongest, rather than uniformly across all MedTech procurement.

Overall, procurement-based interventions should focus on **improving demand signalling rather than enforcing local preference**, thereby supporting local participation while maintaining value for money and supply continuity.

2. Regulatory and Certification Support

Regulatory compliance and certification costs are essential to safeguarding patient safety but represent a **disproportionate burden for smaller or newer manufacturers**, particularly in the absence of scale economies. The policy objective is therefore not to lower standards, but to **improve transparency, efficiency, and access** within existing regulatory frameworks.

- **Enhance Transparency and Efficiency in Regulatory Processes**

Greater clarity regarding **regulatory requirements, timelines, expectations and how MedTech regulation differs from the pharmaceutical sector** can materially reduce compliance risk, uncertainty for manufacturers and streamline processes. Early engagement between regulators and industry, clear guidance on documentation requirements, and predictable review processes can lower transaction costs without compromising regulatory integrity.

Such measures are particularly important for **Class B and selected Class C devices**, where regulatory pathways are more complex but still manageable for local firms with appropriate support.

- **Facilitate Access to Shared Testing, Validation, and Certification Resources**

The absence of **locally accredited testing and validation facilities** increases costs and extends time to market for local manufacturers, who must rely on offshore services. Facilitating access to shared or pooled resources, whether physical infrastructure, advisory services, or validation support, could significantly lower entry barriers, especially for SMEs.

Shared certification resources align with the principle of **system-level enablement**, recognising that compliance capacity benefits the entire sector rather than individual firms alone. Such mechanisms are particularly relevant for priority categories where local capability exists but scale and compliance costs limit expansion.

3. Industry Capability and Skills Development

Skills availability and production capability remain uneven across the MedTech sector, constraining progression from basic manufacturing and assembly into higher-value activities, such as manufacture of higher-risk classification products. Addressing these gaps requires **targeted, demand-aligned interventions** rather than generic training programmes.

- **Support Targeted Skills Development Aligned to Priority Categories**

Skills development efforts are most effective when aligned to **specific product categories and value chain roles**, such as quality assurance, regulatory affairs, toolmaking, and equipment maintenance. Focusing on priority categories identified through demand mapping ensures that skills investments are matched to realistic localisation pathways.

Collaboration between industry, training institutions, and regulators can help ensure that curricula and certification programmes reflect actual market needs and regulatory requirements.

- **Encourage Incremental Upgrading of Quality and Production Systems**

Rather than expecting firms to leap directly to world-class manufacturing across all dimensions, policy support should encourage **incremental upgrading of quality management systems, manufacturing processes, and compliance capability**. This approach reduces risk, allows learning by doing, and supports gradual integration into more complex value chain activities.

Incremental upgrading is particularly relevant in hybrid localisation models, where assembly or packaging can serve as a stepping stone toward deeper manufacturing participation over time.

4. Data, Coordination, and Governance

A recurring constraint identified across the analysis is the **fragmentation of market, procurement, and utilisation data**, which makes it challenging to establish an accurate view of the market and limits coordinated planning and evidence-based decision-making.

- **Improve Availability and Integration of Market and Utilisation Data**

There is currently no integrated view of MedTech demand, sourcing, utilisation, supplier participation and pricing across the public health system. Improving data availability through standardised reporting, integration of existing datasets and targeted data-sharing mechanisms would strengthen the ability of policymakers, procurers and manufacturers to identify scale opportunities, forecast demand and monitor localisation outcomes. Increased

accuracy and transparency of market data will also contribute to improved investor confidence.

A key finding of this study is that current procurement, utilisation and expenditure datasets, including LOGIS, BAS and NHLS, operate largely as independent systems with limited interoperability and no unified mechanism for linking procurement transactions, utilisation patterns, supplier information and manufacturing activity. This fragmentation limits visibility of national demand, constrains product-level market analysis and makes it difficult to assess procurement efficiency, localisation performance and supply security across medical devices and IVDs. In addition, inconsistencies in product categorisation and coding across datasets, limited granularity of product descriptions, and the absence of a standardised taxonomy for medical devices and IVDs restrict the ability to compare products across systems. The lack of consistently reported procurement volumes and unit pricing further limits assessment of purchasing efficiency, price variation, utilisation trends, and market size at the individual product level, reducing the ability to conduct robust demand forecasting and supplier performance analysis.

Systems integration across public entities that deal with MedTech procurement using uniform data standards is particularly important for determining an accurate market view that differentiates between locally manufactured products and imported products supplied by local distributors, ensuring that localisation outcomes are accurately measured and evaluated across both the public and private sectors. A practical first step under the Masterplan would be to establish a multi-stakeholder initiative to develop a common MedTech master data framework, including standardised product classifications, supplier identifiers, localisation indicators, and reporting requirements aligned with international standards.

The initiative should draw on expertise in health procurement and supply chain management, MedTech and IVD market analysis, industrial policy and localisation, health information systems, master data management, data governance, health economics, regulatory affairs, customs and trade statistics, digital health, and advanced data analytics. Representation from procurement authorities, health departments, academia, healthcare providers, regulatory bodies, manufacturers, distributors, industry associations, and data custodians would help ensure practical implementation and broad adoption. Over time, establishing a unified MedTech market intelligence framework linking procurement, utilisation, regulatory, manufacturing, and supplier information would support evidence-based decision-making, improve demand forecasting, strengthen localisation planning, and provide a more robust basis for industrial policy, investment prioritisation, and market monitoring. Appropriate mechanisms would need to be developed to address commercial

confidentiality, data ownership, privacy requirements, and data-sharing arrangements, particularly in the private sector.

There is also a significant opportunity to utilise artificial intelligence (AI) and advanced analytics to strengthen procurement and market intelligence capabilities across the health sector. However, realising this opportunity would first require foundational enablers, including improved data interoperability, data-sharing agreements between key data owners, alignment on product classification standards, and appropriate safeguards for data privacy, commercial confidentiality, and compliance with the Protection of Personal Information Act (POPIA). Subject to these prerequisites, and with buy-in from stakeholders such as National Treasury, provincial health departments, the NHLS and other data custodians, AI-enabled analytical tools could help consolidate procurement, utilisation and expenditure datasets to provide a more comprehensive view of demand across the health system. Such capabilities could support demand forecasting, procurement planning, identification of utilisation and pricing trends, monitoring of supply-chain risks, and assessment of opportunities for localisation. Over time, enhanced data integration and analytics could contribute to more evidence-based decision-making, improved demand aggregation, stronger localisation strategies, and better alignment between healthcare needs, procurement planning and industrial development objectives.

Additionally, strengthening the foundations and policy framework for Health Technology Assessment (HTA) in the MedTech sector could further support evidence-based decision-making that balances procurement considerations, such as localisation, supply security, and local industrial development objectives, with health outcomes. Critical success factors would include access to up-to-date, accurate data that will inform HTA as well as appropriately skilled health economists across the public and private sectors as well as at regulatory agencies that are tasked with such oversight.

- **Clarify Coordination Mechanisms Across Public Institutions**

Multiple public institutions influence MedTech localisation, including those responsible for health service delivery, procurement, industrial policy, regulation, and skills development. Clarifying coordination mechanisms and roles can reduce duplication, improve policy coherence, and accelerate implementation.

Coordination does not imply centralisation; rather, it requires **clear interfaces and shared objectives** across institutions to ensure that demand-side and supply-side interventions reinforce one another.

5. Private Sector Engagement

The private sector plays a critical role in shaping MedTech demand, particularly for high-value and advanced technologies. Engaging private actors constructively is therefore essential to any localisation strategy.

- **Promote Collaborative Supplier Development Initiatives**

Collaborative supplier development, where purchasers, manufacturers, and regulators work jointly to address quality, service, or compliance gaps, can reduce perceived risk and build confidence in local alternatives. Such initiatives are particularly relevant in categories where local firms can meet performance requirements but lack market exposure or service depth.

- **Encourage Voluntary Participation in Pilot Procurement and Localisation Models**

Pilot initiatives provide a low-risk mechanism to test localisation approaches, gather evidence, and refine interventions before scaling. Encouraging voluntary participation by private buyers in pilot procurement or localisation models can generate valuable learning while preserving commercial autonomy.

Pilots are especially appropriate for **assembly, servicing, and aftermarket models** in advanced equipment categories, where full manufacturing is not feasible, but local value capture can improve system resilience.

- **Promote Voluntary Private-Sector Data Sharing and Market Transparency**

A more comprehensive understanding of the South African MedTech market is constrained by limited visibility of private-sector procurement, utilisation, and supplier activity. Encouraging voluntary mechanisms for sharing aggregated and anonymised market data, including procurement volumes, technology adoption trends, and supplier participation, can strengthen market intelligence and support more evidence-based localisation planning.

Section 5: Way Forward

SUMMARY AND CONCLUSION

South Africa is the largest MedTech market on the continent, valued at roughly R29.6 billion in 2025, yet it meets more than 90% of its device demand through imports, with local manufacturing accounting for under 5% of market value. Drawing on SARS trade data, National Treasury BAS and LOGIS procurement records, NHLS annual reports and CMS industry reports and healthcare utilisation annexures, key informant interviews and a supplier survey, the study confirms a structurally import-dependent market, concentrated in advanced surgical, imaging, implantable and diagnostic technologies. Public-sector demand is substantial, concentrated in Gauteng, the Western Cape and KwaZulu-Natal, and much of the fastest growth sits in categories where local capability already exists, including assistive and rehabilitation products, dressings, respiratory accessories, infection prevention and control products, medical furniture and consumables. Local capability, however, remains SME-led, geographically clustered and underutilised, constrained chiefly by high input costs, regulatory burden, fragmented and price-weighted procurement, payment delays and limited local testing and certification infrastructure.

Conclusion

The study's central message is that import dependence is structural rather than transitional, but far from immovable, and that localisation is neither an all-or-nothing proposition nor an end in itself. The most credible path forward is a capability-led, selectively sequenced strategy: consolidating and scaling proven categories (sutures, wheelchairs and assistive devices, gloves, sterilisation consumables, hospital furniture and infusion sets); expanding local manufacturing into higher-value products within partially localised sectors through technology upgrades, skill development, and regulatory support; enabling importers to integrate backward into assembly and manufacturing; and pursuing assembly, servicing and refurbishment where full manufacture is not viable, with rapid diagnostic tests as the sole realistic near-term IVD opportunity. Crucially, no single lever suffices; sustainable outcomes depend on the interaction of clearer demand signalling, proportionate regulatory and certification support, targeted skills development, better integrated data, and constructive private-sector engagement, all delivered through phased piloting, institutional alignment and disciplined risk management around quality, supply continuity and value for money. Applied this way, localisation can simultaneously strengthen health-system resilience, industrial development and economic participation under the Medical Technology Masterplan.

IMPLEMENTATION CONSIDERATIONS



Figure 39: Implementation Considerations

Effective implementation of the proposed policy and market recommendations will depend on **phased sequencing, clarity of institutional roles, and continuous monitoring and learning**. The evidence from the MedTech Demand Mapping and Validation analyses underscores that localisation outcomes are most sustainable when interventions are **incremental, targeted, and aligned to existing institutional mandates**, rather than pursued through broad or accelerated roll-out.

Phased Sequencing and Piloting

Given the heterogeneity of product categories, demand segments, and localisation pathways, implementation should follow a **phased and sequenced approach**. Initial efforts should focus on **priority product categories with the highest feasibility and lowest systemic risk**, particularly high-volume consumables and selected diagnostics where demand is stable, regulatory pathways are manageable, and local capability already exists.

Piloting is a critical implementation mechanism. Pilot procurement or localisation initiatives allow policymakers and market participants to **test assumptions, observe supplier responses, and identify operational bottlenecks** before scaling. This approach is especially important in categories where localisation pathways involve hybrid models (e.g. assembly, packaging, servicing), or where procurement and regulatory adjustments interact in complex ways. Lessons from pilots should be explicitly documented and used to refine subsequent phases.

Institutional Roles and Coordination

Implementation will require **clear delineation of roles across public institutions** involved in health service delivery, procurement, industrial policy, regulation, and skills

development. While multiple institutions have legitimate mandates in the MedTech ecosystem, the absence of coordination can lead to fragmented interventions, duplication, or misaligned incentives.

Clarity on institutional responsibilities is particularly important where **demand-side and supply-side interventions intersect**, such as procurement reforms that aim to improve demand predictability, or regulatory support mechanisms that interact with industrial capability development. Coordination mechanisms should therefore focus on **alignment rather than centralisation**, ensuring that each institution contributes within its mandate while working toward shared localisation objectives.

Risk Management: Quality, Continuity, and Value for Money

Risk management should be a central consideration throughout implementation. The primary risks to be managed include **product quality and patient safety, continuity of supply**, and **value for money** for public and private purchasers.

Quality assurance must remain non-negotiable. Any localisation initiative, whether manufacturing, assembly, or servicing, should operate fully within existing regulatory standards and quality management requirements. Implementation should therefore prioritise regulatory clarity, early engagement with regulators, and support for quality system strengthening, particularly for smaller firms entering new product categories.

Supply continuity is equally critical. Localisation initiatives should not introduce single-supplier dependencies or reduce redundancy in critical product categories. Phased implementation, dual sourcing strategies, and continued access to imports during transition periods are important safeguards to ensure that service delivery is not disrupted.

Value for money considerations should be addressed through **transparent cost comparisons, HTA, lifecycle costing where feasible, and ongoing performance monitoring**. Localisation should not be treated as an end in itself, but as a means to improve supply resilience, economic participation, and long-term system efficiency.

Monitoring, Feedback, and Adaptive Management

Finally, implementation should be accompanied by **ongoing monitoring and adaptive management**. Given data gaps identified in the analysis, early implementation phases should prioritise improving visibility into demand, sourcing patterns, and supplier performance. Monitoring frameworks should be proportionate and focused on a small set of indicators that track localisation progress, supply performance, and unintended consequences.

Feedback loops between procurers, suppliers, regulators, and policymakers are essential to ensure that implementation remains responsive to market realities. Where

interventions are not delivering expected outcomes, adjustments should be made promptly, rather than persisting with predefined approaches.

Overall Consideration

In summary, successful implementation will depend less on the breadth of interventions and more on **sequencing, coordination, and disciplined execution**. A measured, evidence-led approach anchored in pilots, institutional alignment, and risk management will maximise the likelihood that MedTech localisation efforts strengthen local capability while safeguarding health system performance and fiscal discipline.

Annexures

ANNEXURE 1: IMPORT ANALYSIS UTILISING SARS TRADE DATA

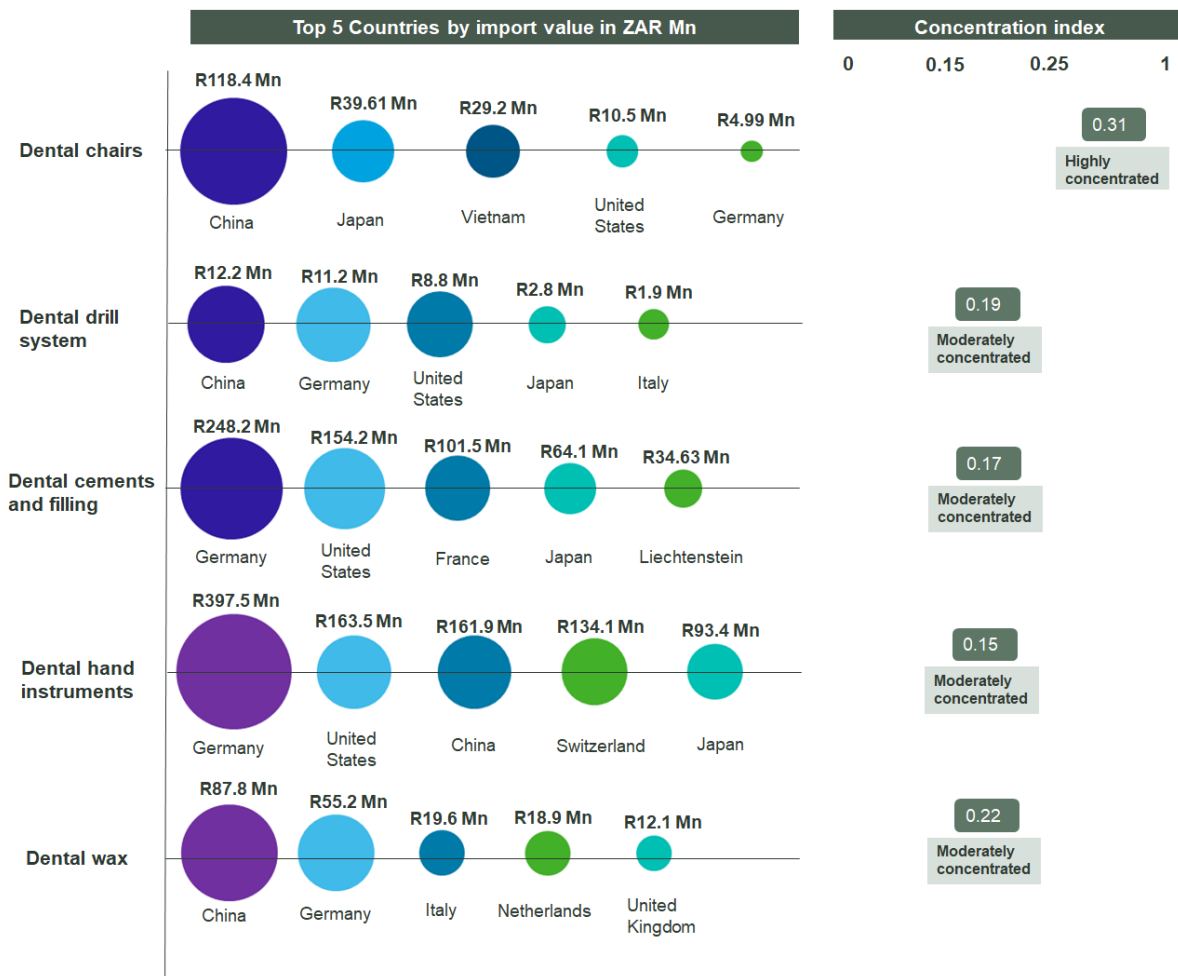
Dental products

South Africa imported approximately R3.2 billion worth of dental products between 2021 and 2025, with the overall dental import market growing at a 9% CAGR. The market is concentrated in a few key product categories, with dental hand instruments, dental fillings & cements and dental prosthetics together accounting for approximately 84% of total dental imports. While dental hand instruments remained the largest import category throughout the period, imports of dental fillings & cements also grew strongly (13% CAGR) and represented a significant share of the market. Equipment-related categories recorded the fastest growth rates, with dental drill systems (23% CAGR) and dental chairs (17% CAGR) demonstrating increasing investment in dental infrastructure and technology, albeit from a smaller import base. In contrast, dental prosthetics (3% CAGR) and dental wax (6% CAGR) exhibited more moderate growth.

Category	Total import value (2021-25)	CAGR
Dental chairs	R229.9 Mn	17%
Dental drill system	R43.8 Mn	23%
Dental fillings and cements	R798.1 Mn	13%
Dental hand instruments	R1296.1 Mn	7%
Dental prosthetics	R622.6 Mn	3%
Dental wax	R229.9 Mn	6%

South Africa's dental products import market remains dependent on a relatively small group of supplier countries, although concentration levels vary by product category. Dental chairs exhibit the highest concentration (HHI 0.314), with China accounting for 51% of imports and the top three suppliers (China, Japan, and Vietnam) contributing 81% of total value, indicating substantial reliance on Asian suppliers. Dental drill systems are more diversified (HHI 0.192), yet the top four suppliers, namely China, Germany, the United States, and Japan, still account for approximately 81% of imports. Dental cements and filling materials represent the larger segment and the lowest concentration (HHI 0.17), with Germany (31%), the United States (19%), and France (13%) leading supply, reflecting a broader sourcing base across advanced manufacturing economies. Dental wax imports show moderate concentration (HHI 0.224), with China maintaining a dominant 38% share and the top five suppliers accounting for 84% of import value. Dental hand instruments are the most diversified

category (HHI 0.148) despite being a large import segment, led by Germany (31%), followed by the United States (13%), China (12%), Switzerland (10%), and Japan (7%); the top five suppliers contribute around 73% of imports, indicating lower concentration and reduced supply risk relative to other dental products. Overall, across the portfolio, 3 to 5 countries are responsible for roughly 80% of import value in most categories. While Germany dominates technologically advanced segments such as dental hand instruments and cements, China emerges as South Africa's most strategically important supplier across the dental sector, leading in multiple categories and playing a critical role in overall supply continuity, making diversification efforts important for mitigating supply-chain and geopolitical risks.



Implantable devices

Imports of implantable devices increased significantly over the period, reaching a cumulative value of R10.1 billion between 2021 and 2025. Artificial joints remained the largest import category, accounting for 55% of total imports, with a 10% CAGR. Other artificial parts of the body showed the strongest growth, recording a 22% CAGR and accounting for 33% of total imports over the five-year period. Pacemaker imports grew more moderately, with a 6% CAGR and 12% of total imports. The sustained growth across all implantable-device categories indicates rising domestic demand for

advanced implant technologies, particularly orthopaedic implants and other artificial body parts, alongside continued reliance on imported products.

Category	Total import value (2021-25)	CAGR
Artificial joints	R5537.9 Mn	10%
Other artificial parts of the body	R3353.2 Mn	22%
Pacemakers	R1253.1 Mn	6%



Imports of implantable devices remain highly concentrated among a small number of supplier countries. For artificial joints, the United States (36%), Switzerland (19%), Ireland (15%), France (8%), and Germany (7%) together account for 85% of total imports, indicating that just five countries supply over 80% of the market. Other artificial parts of the body show a more diversified supply structure, with the top five suppliers accounting for 63% of imports, led by the United States (34%). In contrast, pacemakers exhibit the highest import dependence, with Switzerland (38%) and Germany (24%) dominating supply, while the top five countries contribute 92% of total imports. Supplier concentration is reflected in the HHI values, with pacemakers (0.25) being the most concentrated market, followed by artificial joints (0.20) and other artificial parts (0.15).

Assistive products

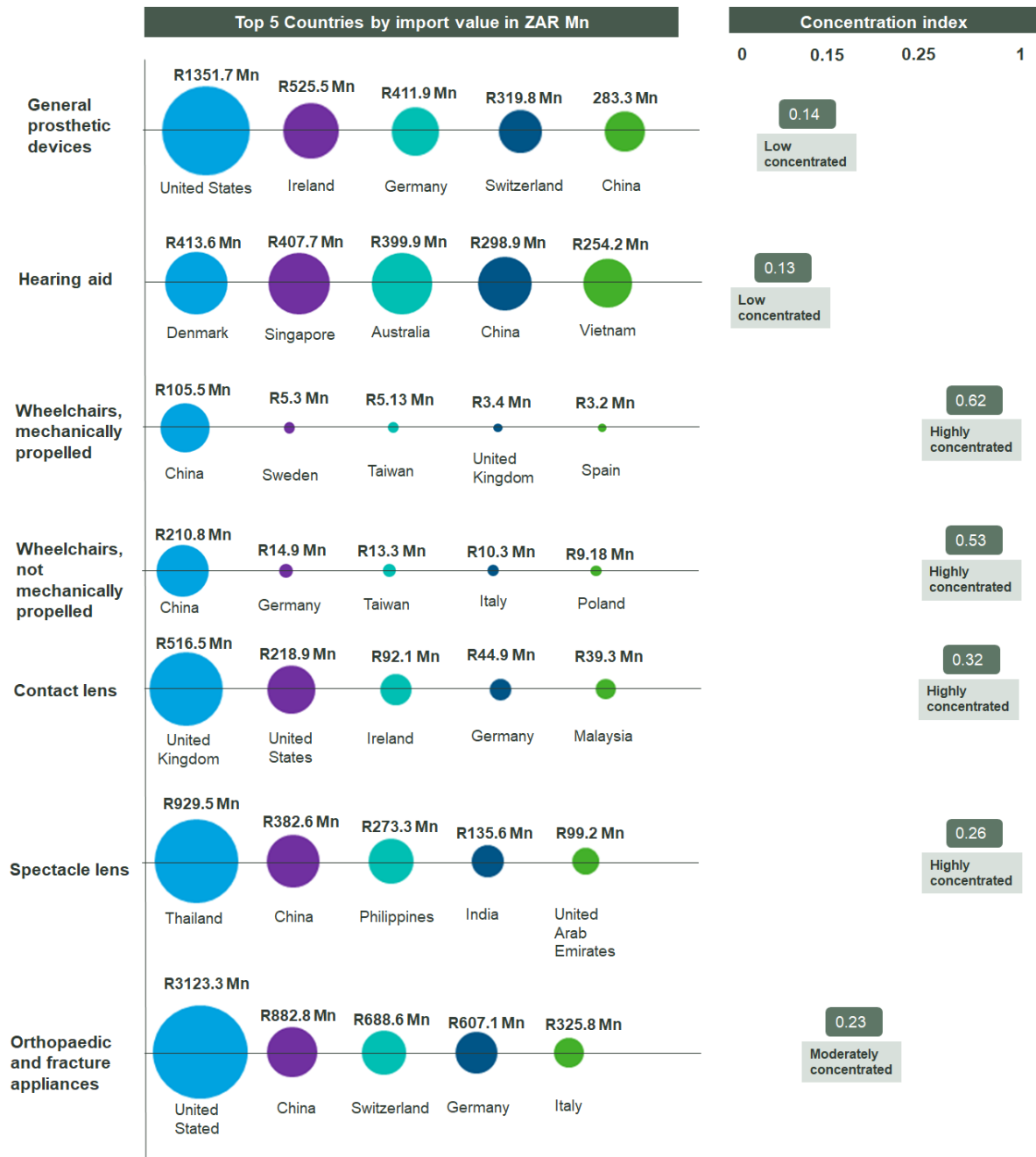
South Africa imported approximately R17.1 billion worth of assistive products between 2021 and 2025. Orthopaedic and fracture appliances represented the largest import category, valued at R7.08 billion (40% of total imports), followed by general prosthetic devices at R4.27 billion (24%), hearing aids at R2.28 billion (13%), spectacle lenses at R2.06 billion (12%), and contact lenses at R1.01 billion (6%). Wheelchairs

accounted for a comparatively small share of total imports, with mechanically propelled wheelchairs valued at R134.9 million and non-mechanically propelled wheelchairs at R292.8 million. Growth trends indicate rising demand for assistive technologies across mobility, hearing and vision care segments. Hearing aids recorded the highest growth rate at 12% CAGR, followed by contact lenses (11% CAGR) and orthopaedic and fracture appliances (9% CAGR), reflecting increasing demand for sensory support and musculoskeletal interventions. Although one of the largest categories by value, general prosthetic devices grew at a more moderate 4% CAGR, suggesting a relatively mature market. Growth in mechanically propelled wheelchairs (3% CAGR) and spectacle lenses (3% CAGR) was comparatively modest, while non-mechanically propelled wheelchairs recorded 7% CAGR, indicating increasing demand for cost-effective mobility solutions. Overall, the strong growth observed in orthopaedic appliances, hearing aids and vision-care products points to expanding healthcare access, an ageing population, increasing prevalence of chronic conditions and disabilities, and continued reliance on imported assistive technologies to meet domestic demand.

Category	Total import value (2021-25)	CAGR
General prosthetic devices	R4269.4 Mn	4%
Hearing aids	R2279.9 Mn	12%
Wheelchairs, mechanically propelled	R134.9 Mn	3%
Wheelchairs, not mechanically propelled	R292.8 Mn	7%
Contact lenses	R1010.8 Mn	11%
Spectacle lenses	R2057.9 Mn	3%
Orthopaedic and fracture appliances	R7078.9 Mn	9%

South Africa's assistive products market exhibits varying levels of import dependence across categories, with a strong reliance on a limited number of supplier countries. General prosthetic devices (HHI 0.14) are relatively diversified, although the United States remains the largest supplier (32%), followed by Ireland (12%), Germany (10%), Switzerland (7%), and China (6%), with Germany (+17% CAGR) and China (+11% CAGR) strengthening their market positions. Hearing aids also demonstrate a diversified supplier base (HHI 0.13), led by Denmark, Singapore, and Australia (18% each), while Denmark (+33% CAGR) and Vietnam (+37% CAGR) are rapidly expanding their presence. Orthopaedic and fracture appliances, the largest assistive product segment by import value, show (HHI 0.23), with the United States dominating supply with a 44% share, followed by China (12%), Switzerland (10%), and Germany (9%); notably, China and Germany both recorded strong growth (+14%), indicating increasing competitiveness despite the continued leadership of US

suppliers. In contrast, South Africa is highly dependent on China for wheelchairs, with China accounting for 78% of mechanically propelled wheelchairs (HHI 0.62) and 72% of non-mechanically propelled wheelchairs (HHI 0.53), creating significant concentration and supply-chain risk. The contact lenses market is moderately concentrated (HHI 0.32), dominated by the United Kingdom (51%) and the United States (22%), while Germany emerged as the fastest-growing supplier (+41%). Spectacle lenses exhibit a more balanced sourcing structure (HHI 0.26), led by Thailand (45%), followed by China (13%) and the Philippines (13%).



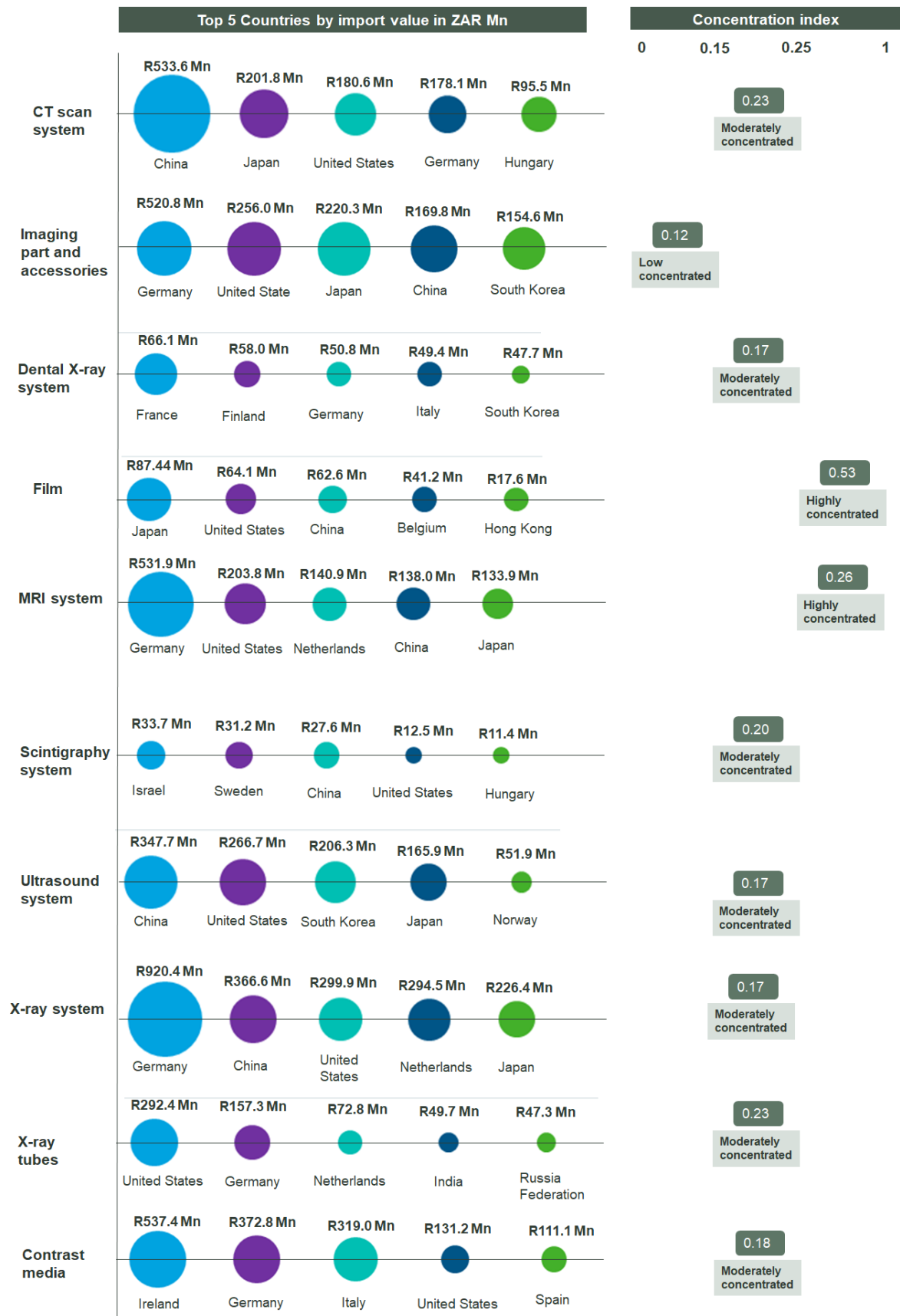
Imaging and nuclear medicine

South Africa imported approximately R12.2 billion worth of imaging and nuclear medicine products between 2021 and 2025. X-ray systems represented the largest import category, accounting for R3.15 billion (26% of total imports), followed by imaging parts and components at R2.00 billion (16%), contrast media at R1.80 billion (15%), CT scan apparatus at R1.33 billion (11%), ultrasound systems at R1.28 billion (10%), and MRI systems at R1.21 billion (10%). Among advanced imaging modalities, CT scan apparatus recorded the strongest growth among major imaging systems at 19% CAGR, followed by MRI systems (16% CAGR) and ultrasound systems (15% CAGR), indicating increasing adoption of advanced diagnostic technologies. Scintigraphy apparatus, a key nuclear medicine technology, accounted for R126.3 million. X-ray tubes contributed R729.6 million and grew at 7% CAGR, reflecting ongoing demand for replacement components and maintenance of imaging infrastructure, while dental x-ray systems accounted for R298.1 million with more modest growth of 3% CAGR. In contrast, medical x-ray film imports totalled R294.1 million and declined by 16% CAGR, reflecting the continued transition from conventional film-based imaging to digital radiography solutions.

Category	Total import value (2021-25)	CAGR
CT scan apparatus	R1334.9 Mn	19%
Dental x-ray system	R298.1 Mn	3%
Imaging parts and components	R1997.0 Mn	7%
Medical x-ray film (Flat)	R294.1 Mn	-16%
MRI system	R1205.9 Mn	16%
Scintigraphy apparatus	R126.3 Mn	93%
Ultrasound system	R1278.2 Mn	15%
X-ray system	R3153.0 Mn	4%
X-ray tubes	R729.6 Mn	7%
Contrast media	R1797.8 Mn	14%

South Africa's imaging and nuclear medicine imports show a moderate level of supplier concentration, with dependency patterns varying significantly across product categories. CT scan system imports are concentrated among a handful of suppliers, led by China (40%). Imaging parts and accessories exhibit the most diversified supply structure, with Germany (26%) maintaining leadership, followed by the United States (13%). Dental x-ray systems show moderate concentration with France (22%), Finland (19%), Germany (17%), Italy (17%), and South Korea (16%) sharing the market relatively evenly. MRI systems are more concentrated, led by Germany (44%), highlighting South Africa's dependence on European suppliers for advanced imaging technologies. In ultrasound systems, China dominates with a 27% share and strong

growth (44% CAGR), while x-ray systems, the largest imaging segment by value, are led by Germany (29%), followed by China (12%). X-ray tubes display dependence on the United States (40%) and Germany (22%), whereas contrast media imports are concentrated among Ireland (30%), Germany (21%), and Italy (18%). In nuclear medicine, scintigraphy system imports are shared primarily among Israel (27%), Sweden (25%), and China (22%). Across the portfolio, the top 3 to 5 countries account for roughly 70-85% of import value in most product categories, indicating that South Africa remains reliant on a relatively small group of technologically advanced supplier countries. Germany emerges as the most critical partner across high-end imaging modalities; China dominates several equipment categories and is gaining share rapidly.

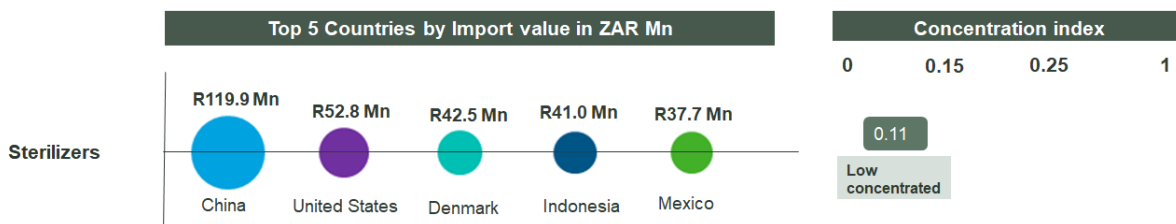


Cleaning / disinfection / Sterilisation equipment

South Africa imported approximately R490.2 million worth of medical and surgical sterilisers between 2021 and 2025. Import values remained relatively stable between 2021 and 2024, before declining in 2025, resulting in a negative CAGR of 8% over the period.

Category	Total import value (2021-25)	CAGR
Sterilisers	R490.2 Mn	-8%

The supplier base remains relatively diversified, as reflected by a low HHI of 0.11. China was the largest supplier, accounting for 24% of total imports, although imports from China declined at -8% CAGR. The United States was the second-largest supplier with an 11% share, but recorded a sharp -56% CAGR, suggesting a significant reduction in market presence. Overall, the steriliser market is less concentrated than many other medical equipment categories, with the top five countries accounting for around 60% of import value.



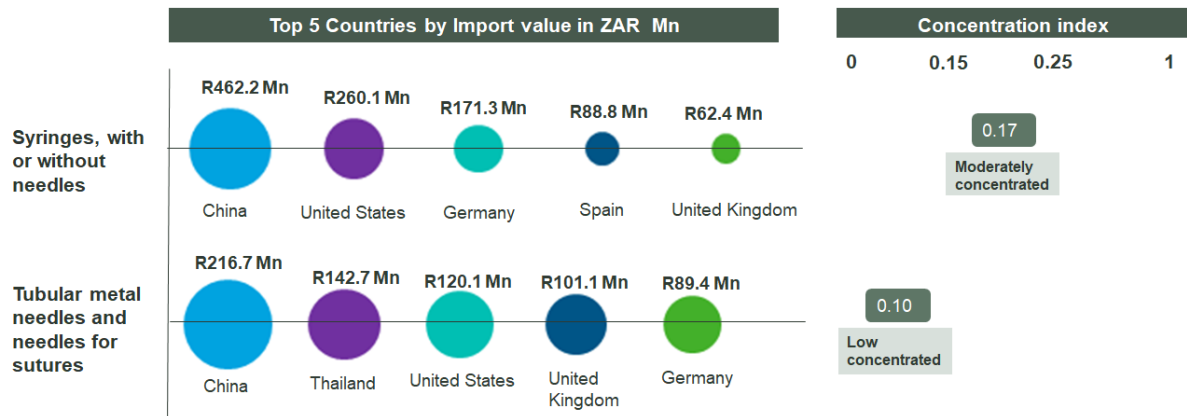
Syringes and needles

South Africa imported approximately R2.5 billion worth of syringes and needles between 2021 and 2025, comprising R1.38 billion in syringes with or without needles and R1.11 billion in tubular metal needles and needles for sutures. Syringes represented the largest import category, accounting for approximately 55% of total imports, while tubular metal needles and needles for sutures contributed the remaining 45%. Import demand for syringes remained relatively stable throughout the period, resulting in a largely flat growth trajectory, suggesting a mature and consistently supplied market. In contrast, imports of tubular metal needles and needles for sutures recorded stronger growth, expanding at a 5% CAGR between 2021 and 2025.

Category	Total import value (2021-25)	CAGR
Syringes with or without needles	R1381.1 Mn	0.0%
Tubular metal needles and needles for sutures	R1112.5 Mn	5%

The syringes market exhibits moderate concentration (HHI 0.17), with China dominating supply at 33% of total imports, followed by the United States (19%) and Germany (12%). The top five supplier countries account for approximately 75% of total

syringe imports. In contrast, the market for tubular metal needles and needles for sutures is more diversified, with a lower concentration level (HHI 0.10). China remains the largest supplier (19%), followed by Thailand (13%), the United States (11%), the United Kingdom (9%), and Germany (8%), with no single country exercising dominant control. Overall, South Africa remains reliant on imported syringes and needles to meet healthcare demand; however, the relatively low concentration levels, particularly for needles and sutures, indicate a diversified supplier base that reduces supply-chain risk. China continues to be the most important individual supplier across both categories.

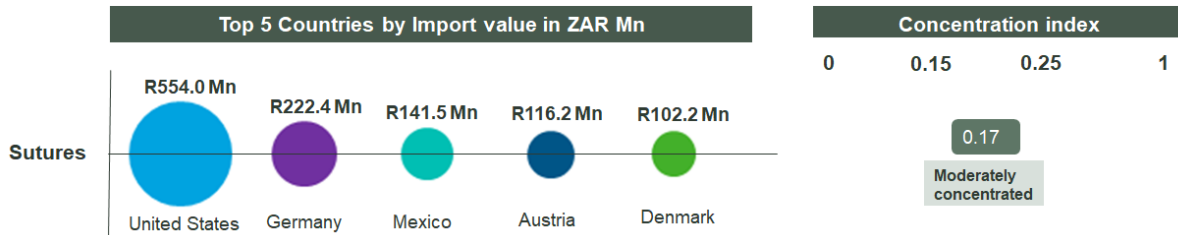


Sutures

South Africa imported approximately R1.6 billion worth of suturing materials between 2021 and 2025, making it a significant category within surgical consumables. Imports increased consistently throughout the period, representing a robust 17% CAGR.

Category	Total import value (2021-25)	CAGR
Sutures	R1575.9 Mn	17%

South Africa's suturing materials import market is moderately concentrated, with an HHI of 0.17, indicating a degree of dependence on a limited group of key suppliers while still maintaining a relatively diversified sourcing base. The United States dominates the market, accounting for 35% of total imports and recording strong growth of 19% CAGR, reinforcing its position as the country's most important supplier of suturing products. Germany ranks second with a 14% share and a solid 10% CAGR, reflecting stable demand for high-quality surgical consumables. Mexico has emerged as a rapidly growing supplier, achieving the highest growth among major sources (23% CAGR) and capturing 9% of imports, while Denmark also recorded robust expansion (28% CAGR) despite a smaller market share of 6%. Austria, with a 7% share, maintained relatively stable import levels over the period. Collectively, the top five supplier countries account for approximately 71% of total suturing material imports, suggesting that South Africa relies heavily on a small group of established medical device manufacturing countries.

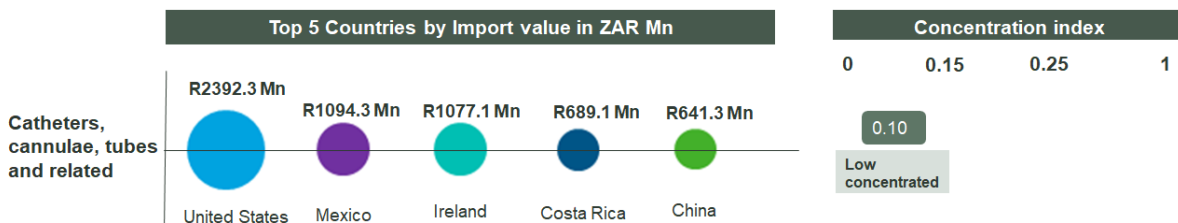


Catheters, cannulae, tubes and related

South Africa's imports of catheters, cannulae, tubes and related products increased strongly with 17% CAGR, resulting in cumulative imports of approximately R10.1 billion over the five-year period, reflecting rising demand for essential consumables used in intravenous therapy, cardiovascular procedures, urinary care, critical care, diagnostics, and other hospital-based interventions.

Category	Total import value (2021-25)	CAGR
Catheters, cannulae, tubes and related	R10110.3 Mn	17%

South Africa's catheters, cannulae, tubes and related products market exhibits low supplier concentration, with an estimated HHI of 0.10, indicating a relatively diversified sourcing structure and limited dependence on any single country. The United States is the dominant supplier, accounting for 24% of cumulative imports between 2021 and 2025 and maintaining steady growth at 11% CAGR. Mexico and Ireland are the next largest suppliers, each contributing approximately 11% of total imports. China, while representing a smaller share (6%), expanded rapidly at 21% CAGR, indicating increasing competitiveness in this segment. Collectively, the top five suppliers account for approximately 59% of total imports, suggesting that the market is significantly less concentrated than many other medical device categories and is supported by a broad international supplier base.



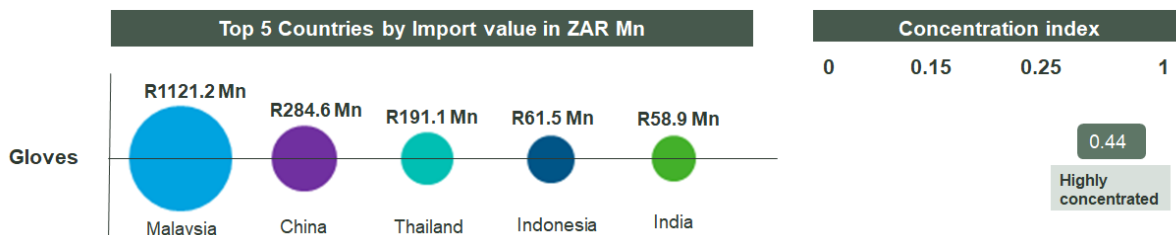
Infection prevention and control: gloves

South Africa imported approximately R1.8 billion worth of gloves between 2021 and 2025. Imports declined significantly between 2021 and 2025, resulting in a negative CAGR of 16% over the period. The sharp decline reflects the normalisation of demand following the COVID-19 pandemic, during which healthcare systems globally increased procurement of personal protective equipment (PPE), including medical gloves. Overall, while import volumes have moderated from pandemic-driven peaks, South Africa remains reliant on imported gloves to meet domestic healthcare demand,

with imports continuing to play a vital role in supporting healthcare service delivery and patient safety.

Category	Total import value (2021-25)	CAGR
Gloves	R1781.5 Mn	-16%

South Africa's medical gloves import market is highly concentrated, with a pronounced dependence on a single supplier country. Between 2021 and 2025, Malaysia represents 63% of total glove imports, making it by far the dominant source of supply. The market concentration is reflected in the relatively high HHI of 0.44, indicating elevated supply-chain risk and significant reliance on Malaysian manufacturers. Despite this dominant position, imports from Malaysia declined at a -18% CAGR, mirroring the overall contraction in glove imports following the normalisation of demand after the COVID-19 pandemic. China ranked as the second-largest supplier with a 16% share, followed by Thailand (11%), while Indonesia and India each contributed around 3% of imports. Collectively, the top three supplier countries (Malaysia, China, and Thailand) accounted for approximately 90% of total glove imports, demonstrating a strong Pareto effect and highlighting the concentration of supply within Southeast Asia.



Dressings, gauzes, bandages, pads

South Africa imported approximately R4.5 billion worth of medical dressings between 2021 and 2025, comprising R2.18 billion in adhesive dressings and R2.30 billion in non-adhesive dressings. Non-adhesive dressings accounted for a slightly larger share of total imports (51%) compared with adhesive dressings (49%). Both categories exhibited strong and sustained growth over the period, reflecting increasing demand for wound care products across the healthcare system. Adhesive dressings recorded a robust CAGR of 15%, while non-adhesive dressings grew at 13% CAGR, indicating expanding utilisation of wound management products and continued growth in demand for advanced wound care solutions.

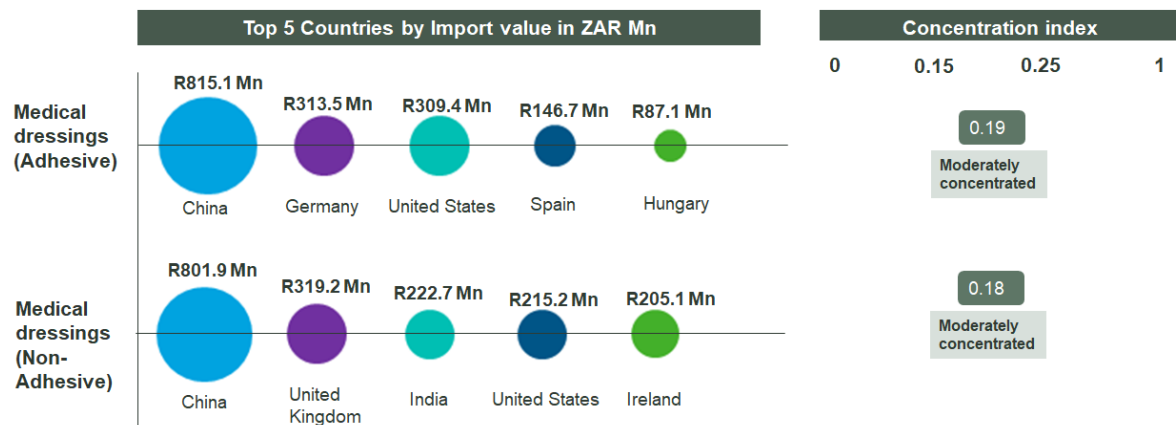
Category	Total import value (2021-25)	CAGR
Medical dressings (Adhesive)	R2179.7 Mn	15%

**Medical dressings
(Non-adhesive)**

R2302.4 Mn

13%

South Africa's medical dressings market is moderately concentrated, with China emerging as the leading supplier in both adhesive and non-adhesive segments. For adhesive dressings, China accounts for 37% of imports, followed by Germany and the United States (14% each), while for non-adhesive dressings, China holds a 35% share, ahead of the United Kingdom (14%) and India (10%). Concentration levels remain moderate (HHI 0.19 for adhesive and 0.18 for non-adhesive dressings), indicating manageable supply risk despite reliance on a limited number of countries. The top five supplier countries account for approximately 76-77% of total imports across both categories. Growth trends further highlight strengthening demand and supplier diversification, with China recording strong growth in adhesive dressings (29% CAGR), while Ireland (32% CAGR) and the United States (29% CAGR) gained significant share in non-adhesive dressings. Overall, South Africa remains heavily dependent on imported dressings, with China serving as the most strategically important supplier, although the presence of multiple growing supplier countries helps mitigate concentration risk.

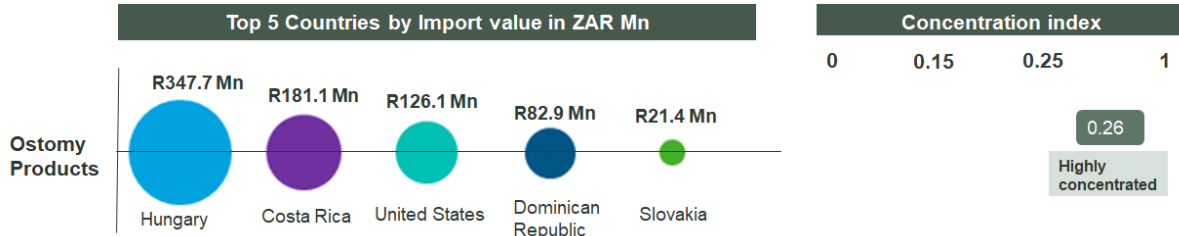

Collection devices

South Africa imported approximately R831.3 million worth of ostomy products between 2021 and 2025. Imports remained relatively stable throughout the period, with a modest 4% CAGR.

Category	Total import value (2021-25)	CAGR
Ostomy products	R831.3 Mn	4%

South Africa's ostomy products import market is highly concentrated, with an HHI of 0.26, indicating a meaningful reliance on a small number of supplier countries. Hungary dominates the market, accounting for 42% of total imports, making it the most strategically important supplier despite a modest decline in imports (-4% CAGR). Costa Rica is the second-largest supplier with a 22% share and strong growth of 22%

CAGR, suggesting a rapidly expanding role in South Africa's ostomy product supply chain. The United States contributes 15% of imports and grew at 13% CAGR, while the Dominican Republic accounts for 10% and recorded robust growth of 16% CAGR. Collectively, the top four supplier countries account for approximately 89% of total import value.

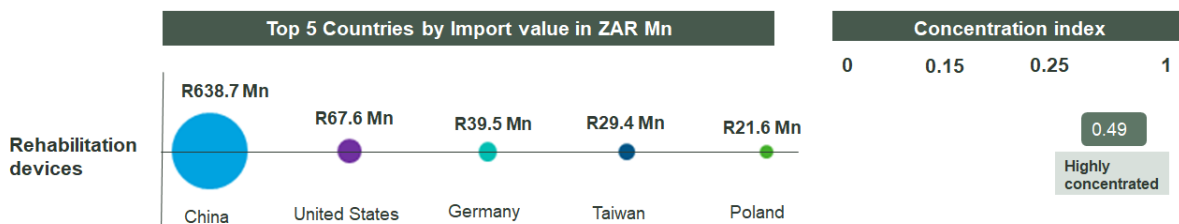


Rehabilitation devices

South Africa imported approximately R924.7 million worth of rehabilitation devices between 2021 and 2025, with a steady 6% CAGR over the period. Import growth was relatively consistent, with demand strengthening particularly after 2022, reflecting increasing utilisation of rehabilitation products to support recovery from injury, chronic disease management, ageing-related conditions, and post-operative care.

Category	Total import value (2021-25)	CAGR
Rehabilitation devices	R924.7 Mn	6%

South Africa's rehabilitation devices import market is highly concentrated, with a substantial dependence on China, which accounted for 69% of total imports between 2021 and 2025 and recorded a healthy 9% CAGR. The high concentration is reflected in the HHI of 0.49, indicating elevated supply-chain risk and a strong reliance on a single supplier country. Overall, South Africa remains heavily dependent on imported rehabilitation devices, with China serving as the dominant supplier.



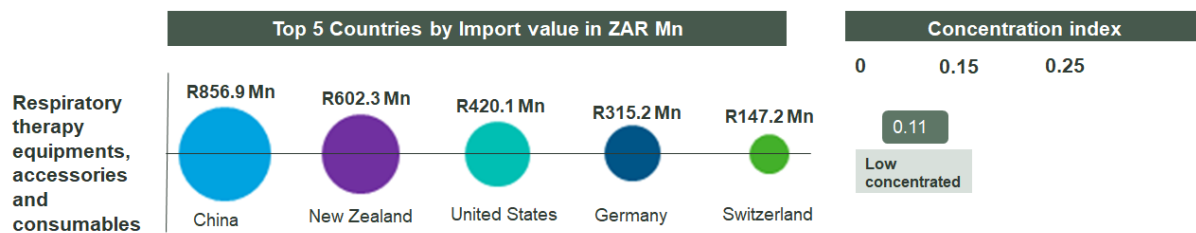
Respiratory therapy equipment and accessories

South Africa imported approximately R3.6 billion worth of respiratory therapy equipment, accessories, and consumables between 2021 and 2025. Imports declined from 2021 to 2025, corresponding to a modest -2% CAGR. The contraction primarily reflects the normalisation of demand following the COVID-19 pandemic, when procurement of respiratory equipment such as oxygen therapy devices, masks, tubing,

humidifiers, and related consumables surged globally. Overall, the market remains significant in value and highlights South Africa's continued reliance on imported respiratory therapy technologies and consumables to support healthcare service delivery and patient care.

Category	Total import value (2021-25)	CAGR
Respiratory therapy equipment, accessories and consumables	R3633.6 Mn	-2%

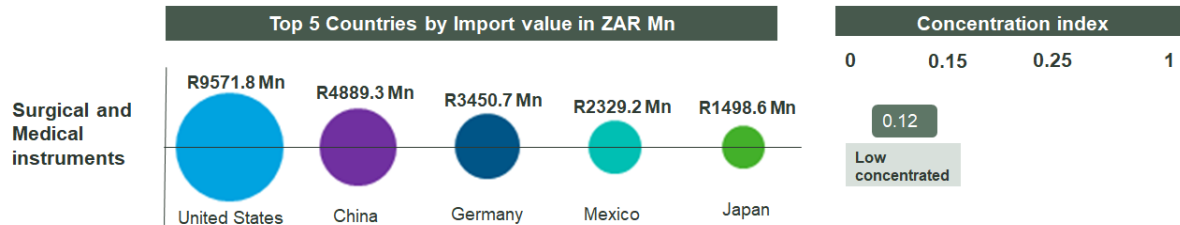
South Africa's respiratory therapy equipment, accessories, and consumables import market is relatively well diversified, with a low HHI of 0.11, indicating limited supplier concentration and reduced dependence on any single country. China is the largest supplier, accounting for 24% of total imports (although imports from China declined at a -11% CAGR, reflecting normalisation of demand following the pandemic period). New Zealand is the second-largest supplier with a 17% share and a positive 3% CAGR, followed by the United States (12%), which also recorded 3% CAGR growth. Germany (9%) and Switzerland (4%) remain important suppliers despite declining import trends. The top five supplier countries account for approximately 66% of total import value, indicating that South Africa sources respiratory products from a broad range of countries rather than relying excessively on a small group of suppliers. From a Pareto perspective, more than five countries are required to reach 80% of imports, highlighting a diversified sourcing structure compared with several other medical device categories. Overall, while South Africa remains heavily dependent on imports to meet demand for respiratory therapy products, the low concentration level and balanced supplier mix enhance supply chain resilience and reduce vulnerability to disruptions from any single exporting country.



Surgical and medical instruments

South Africa imported approximately R34.3 billion worth of surgical and medical instruments, between 2021 and 2025, with 9% CAGR. The market is relatively diversified, as reflected by a low HHI of 0.12, indicating limited supplier concentration and relatively low supply-chain risk. The United States is the largest supplier, accounting for 28% of total imports, followed by China (14%), Germany (10%), Mexico (7%), and Japan (4%). The top five supplier countries account for approximately 63% of total imports suggesting a broad and diversified sourcing base.

Category	Total import value (2021-25)	CAGR
Surgical and medical instruments	R34293.8 Mn	9%

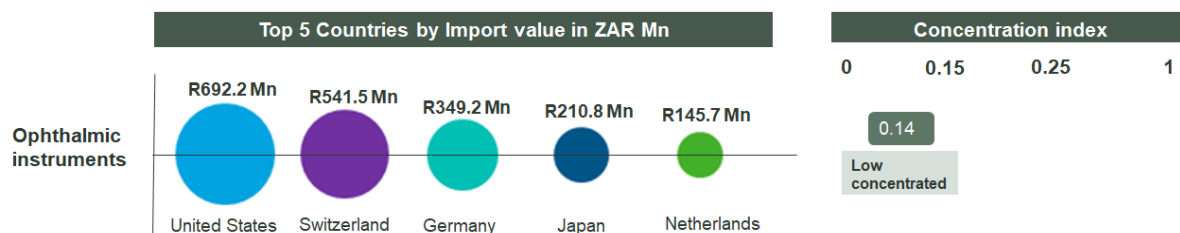


Ophthalmic instruments

South Africa imported approximately **R2.7 billion** worth of **ophthalmic instruments** between 2021 and 2025, with moderate **4% CAGR** over the period.

Category	Total import value (2021-25)	CAGR
Ophthalmic instruments	R2684.7 Mn	4%

South Africa's **ophthalmic instruments** import market is relatively diversified, with a low **HHI of 0.14**, indicating moderate concentration and limited dependence on any single supplier country. The **United States** is the largest supplier, accounting for **26% of total imports** between 2021 and 2025, followed by **Switzerland (20%)**, **Germany (13%)**, **Japan (8%)**, and the **Netherlands (5%)**. Both the United States and Switzerland recorded strong growth (**13% CAGR** each). The **top five supplier countries account for approximately 72% of total imports**, indicating that while a small group of countries dominates supply, the market remains less concentrated than many other medical device categories.

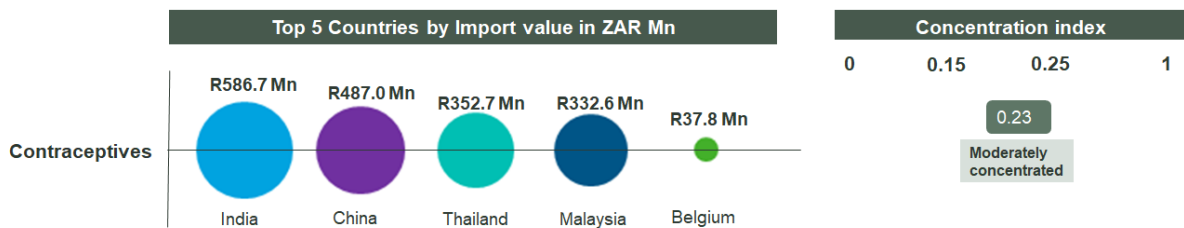


Contraceptives

South Africa imported approximately **R1.9 billion** worth of **contraceptives** between 2021 and 2025, with healthy **7% CAGR** over the period.

Category	Total import value (2021-25)	CAGR
Contraceptives	R1869.1 Mn	7%

South Africa's contraceptives import market is moderately concentrated, with an HHI of 0.23, indicating a meaningful dependence on a limited number of Asian suppliers. India is the largest supplier, accounting for 31% of total imports and recording an exceptional 62% CAGR, significantly strengthening its position over the period. China follows with a 26% share, maintaining a relatively stable market presence (-1% CAGR), while Thailand (19%) and Malaysia (18%) experienced declining imports, with CAGRs of -13% and -19%, respectively. Together, the top four supplier countries account for approximately 94% of total imports. Overall, South Africa remains highly dependent on imports for contraceptives, with supply concentrated primarily among Asian manufacturers.

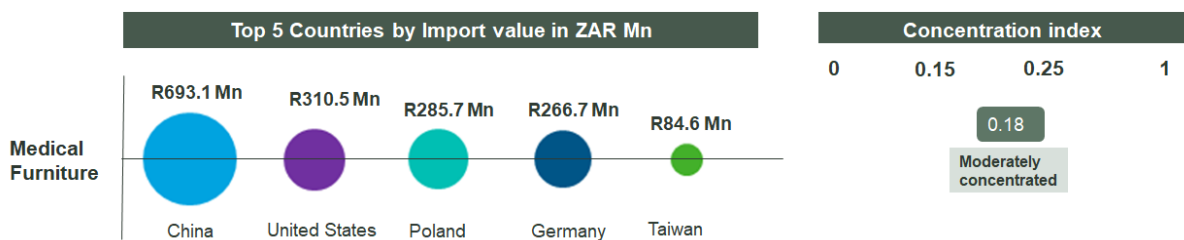


Medical furniture

South Africa imported approximately R2.1 billion worth of hospital and medical furniture between 2021 and 2025, with annual imports remaining relatively stable throughout the period, resulting in a modest 1% CAGR, indicating a mature market with steady replacement and expansion demand rather than rapid growth.

Category	Total import value (2021-25)	CAGR
Medical furniture	R2063.4 Mn	1%

South Africa's medical furniture import market is characterised by moderate concentration, with an HHI of 0.18, indicating some dependence on a limited number of suppliers but a lower level of concentration than many other medical device categories. China is the dominant supplier, accounting for 34% of total imports between 2021 and 2025, although imports from China declined marginally (-1% CAGR). The United States (15%), Poland (14%), and Germany (13%) form a strong second tier of suppliers. Collectively, the top five supplier countries account for approximately 80% of total imports.

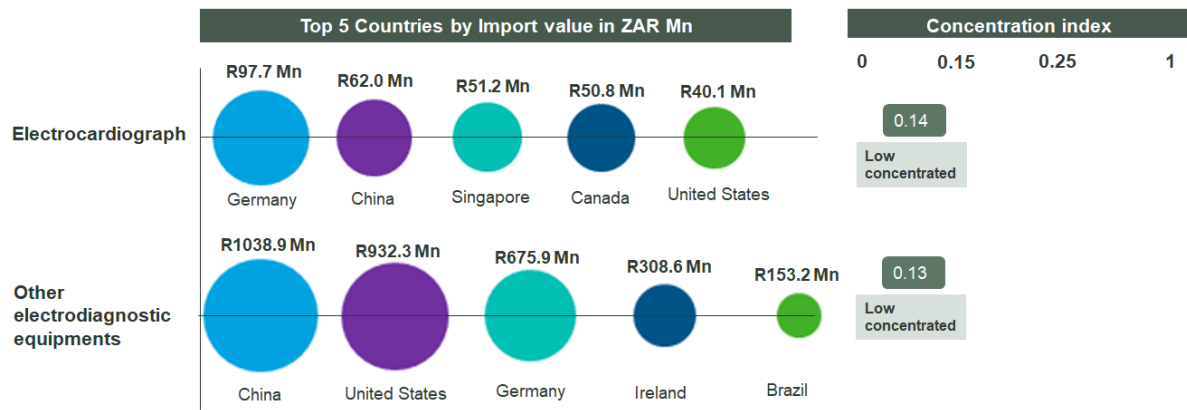


Electrocardiographs and other electrodiagnostic equipment

South Africa imported approximately R4.9 billion worth of electrodiagnostic equipment between 2021 and 2025, comprising R384.4 million in electrocardiographs (ECGs) and R4.50 billion in other electrodiagnostic equipment. Import growth patterns differed substantially between the two categories. Electrocardiographs recorded a modest CAGR of 1%, suggesting a mature and relatively stable market, whereas other electrodiagnostic equipment grew at a robust CAGR of 16%, indicating strong expansion in demand for advanced diagnostic and patient monitoring technologies. This category encompasses a broad range of devices, including patient monitoring systems, electroencephalographs (EEGs), electromyographs (EMGs), diagnostic monitoring equipment and other technologies used to assess physiological functions. Overall, the strong growth observed within the broader electrodiagnostic equipment category highlights increasing investment in diagnostic and monitoring technologies and continued reliance on imported products to support South Africa's growing healthcare needs.

Category	Total import value (2021-25)	CAGR
Electrocardiographs	R384.4 Mn	1%
Other electrodiagnostic equipment	R4504.3 Mn	16%

South Africa's electrodiagnostic equipment market exhibits a relatively diversified supplier structure across both product segments, with low concentration levels and limited dependence on a single country. For electro-cardiographs (ECGs), the market has a low HHI of 0.14, with Germany emerging as the leading supplier, accounting for 25% of imports, followed by China (16%), Singapore (13%), Canada (13%), and the United States (10%). China recorded the strongest growth among major suppliers (21% CAGR). The top five suppliers accounted for approximately 77% of total ECG imports, indicating no single country dominating supply. For other electrodiagnostic apparatus, concentration is similarly low (HHI 0.13), led by China (23%), the United States (21%), and Germany (15%). More than five countries are required to reach 80% of import value, reflecting a broad and resilient sourcing base. Overall, South Africa remains highly dependent on imports for electrodiagnostic technologies, but the low concentration indices, balanced supplier mix, and strong participation from North America, Europe, and Asia reduce supply-chain risk and provide greater resilience compared with more concentrated medical device categories.

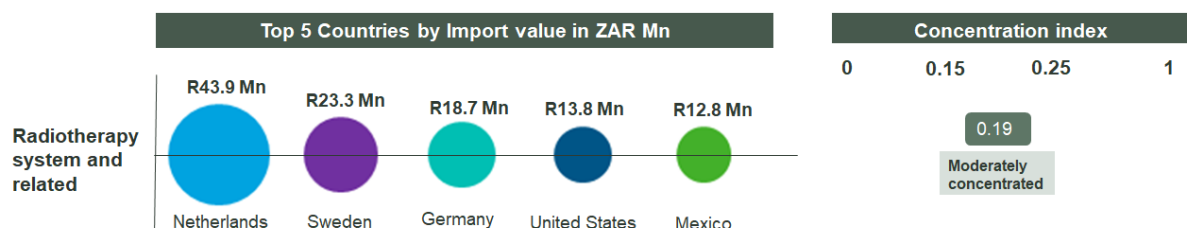


Radiotherapy related equipment

South Africa imported approximately **R130.2 million** worth of **radiotherapy systems and related** equipment between 2021 and 2025, making it a relatively small but strategically important segment of the medical technology market.

Category	Total import value (2021-25)	CAGR
Radiotherapy system and related	R130.2 Mn	54%

South Africa's **radiotherapy systems** import market is **moderately concentrated**, with an **HHI of 0.19**, indicating a meaningful reliance on a small group of specialised supplier countries but not excessive dependence on a single source. The **Netherlands dominates the market**, accounting for **34% of total imports**. **Sweden** is the second-largest supplier with an **18% share**, followed by **Germany (14%)**, **United States (11%)**, and **Mexico (10%)**. The **top five suppliers account for approximately 87% of total imports**. Given the highly specialised nature of radiotherapy systems and the limited number of global manufacturers, this concentration is generally expected. Overall, South Africa remains heavily dependent on imported radiotherapy technologies, with the Netherlands emerging as the most important supplier, while the rapid growth of Germany and Sweden suggests expanding procurement from multiple advanced oncology equipment manufacturing hubs, helping to partially mitigate supplier concentration risk.

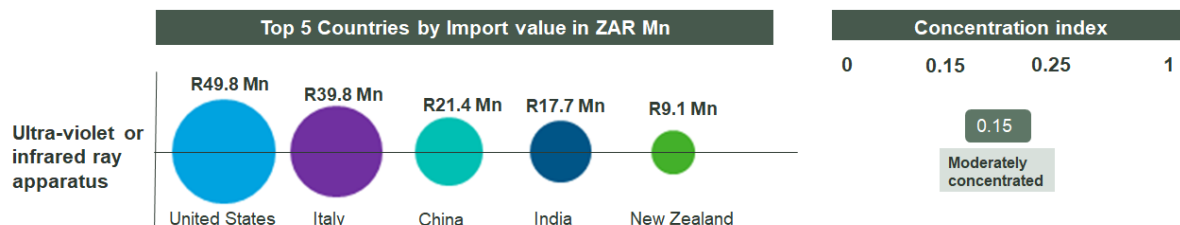


Ultraviolet and infrared ray system including parts and accessories

South Africa imported approximately **R184.7 million** worth of **ultra-violet (UV) or infra-red (IR) ray systems, including parts and accessories**, between 2021 and 2025, representing a solid **11% CAGR** over the period.

Category	Total import value (2021-25)	CAGR
Ultra-violet (UV) or infra-red (IR) ray systems, including parts and accessories	R184.7 Mn	11%

South Africa's ultra-violet (UV) or infra-red (IR) ray systems, including parts and accessories import market is moderately concentrated, with an HHI of 0.15, indicating a balanced supplier structure and relatively low dependence on any single country. The United States is the largest supplier, accounting for 27% of total imports, followed closely by Italy (22%), China (12%), India (10%), and New Zealand (5%). Italy and China have strengthened their market positions significantly, recording strong growth rates of 32% CAGR and 27% CAGR, respectively. In contrast, imports from India declined sharply (-30% CAGR), reducing its relative importance in the supply chain. More than five countries are still required to reach 80% of total import value, indicating a broader supplier base than in highly concentrated medical device categories. Overall, South Africa remains dependent on imported UV and IR medical systems and accessories, but the moderate concentration level, coupled with strong participation from suppliers across North America, Europe, Asia, and Oceania, provides a relatively resilient and diversified sourcing structure.



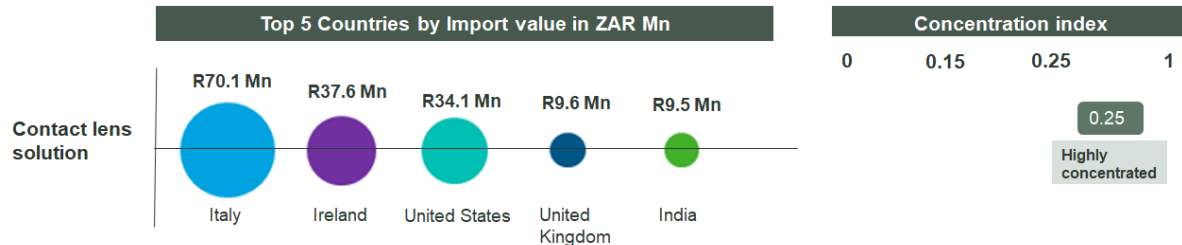
Contact lens solution

South Africa imported approximately **R177.8 million** worth of **contact lens solution** between 2021 and 2025, representing a strong **14% CAGR** over the period.

Category	Total import value (2021-25)	CAGR
Contact lens solution	R177.8 Mn	14%

South Africa's contact lens solution import market is highly concentrated, with an HHI of 0.25. Italy dominates the market, accounting for 39% of total imports and recording strong growth of 15% CAGR, making it the most strategically important supplier.

Ireland is the second-largest supplier with a 21% share and an equally strong 15% CAGR, while the United States contributes 19% of imports and grew at a more moderate 8% CAGR. Together, these three countries account for approximately 79% of total import value, meaning just three countries are responsible for nearly 80% of South Africa's contact lens solution imports. Overall, South Africa remains highly dependent on imported contact lens care products, with supply concentrated among a few key international manufacturers.

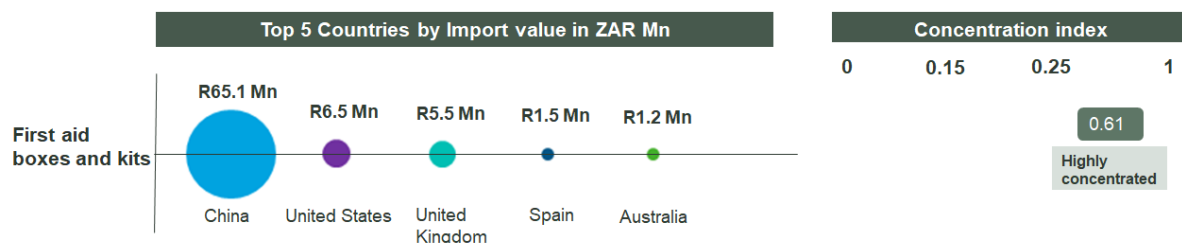


First aid boxes and kits

South Africa imported approximately **R84.3 million** worth of **first-aid boxes and kits** between 2021 and 2025. Imports remained largely stable throughout the period, resulting in a modest **1% CAGR**. The limited growth suggests a mature market characterised by recurring replacement demand rather than significant expansion.

Category	Total import value (2021-25)	CAGR
First aid boxes and kits	R84.3 Mn	1%

South Africa's first-aid boxes and kits import market is highly concentrated, with a very high HHI of 0.61, indicating significant dependence on a single supplier country. China overwhelmingly dominates the market, accounting for 77% of total imports between 2021 and 2025. The United States (8%) and the United Kingdom (7%) are distant secondary suppliers. The top three supplier countries (China, United States, and United Kingdom) account for approximately 92% of total imports, demonstrating a very concentrated sourcing structure.



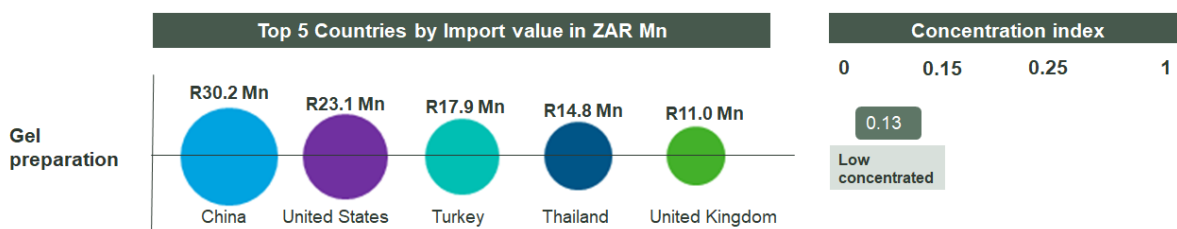
Gel preparations

South Africa imported approximately R130.7 million worth of gel preparations between 2021 and 2025, with imports more than doubling from 2021 to 2025, resulting in a strong 23% CAGR. The category demonstrated consistent year-on-year growth throughout the period, indicating rapidly expanding demand across healthcare

settings. Gel preparations include a range of products used for ultrasound procedures, medical examinations, wound care, therapeutic applications, and other clinical treatments, making them essential consumables in routine healthcare delivery.

Category	Total import value (2021-25)	CAGR
Gel preparations	R130.7 Mn	23%

South Africa's gel preparations import market is relatively diversified, with a low HHI of 0.13, indicating limited supplier concentration and a resilient sourcing structure. China is the largest supplier, accounting for 23% of total imports and recording strong growth of 72% CAGR, significantly increasing its market presence over the period. The United States follows closely with an 18% share while Turkey (14%) and Thailand (11%) emerged as rapidly expanding suppliers, growing at 48% CAGR and 56% CAGR, respectively. The top five supplier countries account for approximately 74% of total imports. Overall, South Africa remains dependent on imported gel preparations, but the low concentration level, balanced supplier mix, and strong growth across multiple countries reduce supply-chain risk and suggest an increasingly diversified sourcing base for this rapidly growing healthcare consumables segment.

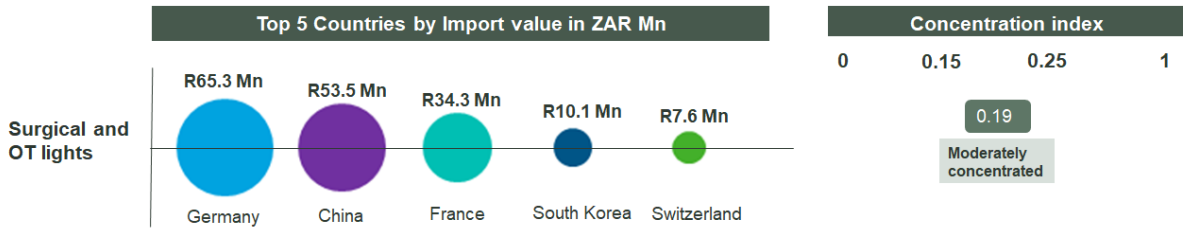


Surgical and operation theatre (OT) lights

South Africa imported approximately R212.8 million worth of surgical and operating theatre (OT) lights between 2021 and 2025, with a moderate 5% CAGR over the period.

Category	Total import value (2021-25)	CAGR
Surgical and OT lights	R212.8 Mn	5%

South Africa's surgical and operating theatre (OT) lights import market is moderately concentrated, with an HHI of 0.19, indicating a reliance on a limited number of established suppliers while maintaining some degree of diversification. Germany is the leading supplier, accounting for 31% of total imports and recording solid growth of 29% CAGR, reinforcing its position as the primary source of advanced surgical lighting systems. China follows closely with a 25% share although imports remained relatively stable over the period, while France contributed 16% of imports and maintained modest growth. Together, the top three supplier countries account for approximately 72% of total imports, and the top five suppliers account for around 81% of total imports.



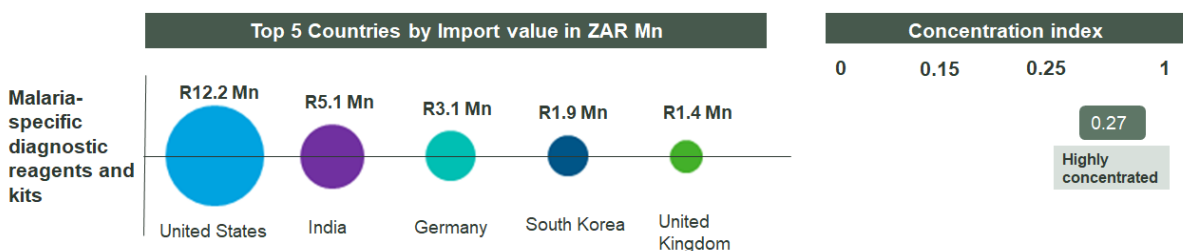
In vitro diagnostic reagents and kits

Malaria-specific diagnostic reagents and kits

South Africa imported approximately R26.6 million worth of malaria-specific diagnostic reagents and kits between 2021 and 2025, with a 61% CAGR, making it one of the fastest-growing diagnostic segments.

Category	Total import value (2021-25)	CAGR
Malaria-specific diagnostic reagents and kits	R26.6 Mn	61%

South Africa's malaria-specific diagnostic reagents and kits import market is highly concentrated, with an HHI of 0.27, indicating a relatively high reliance on a small number of suppliers. The United States dominates the market, accounting for 46% of total imports and recording a strong 62% CAGR. India is the second-largest supplier with a 19% share and is the fastest-growing major supplier, suggesting rapidly increasing market penetration. The top three suppliers (United States, India, and Germany) account for approximately 77% of total import value, and the top five suppliers contribute nearly 89%, highlighting South Africa's dependence on a limited number of international sources.

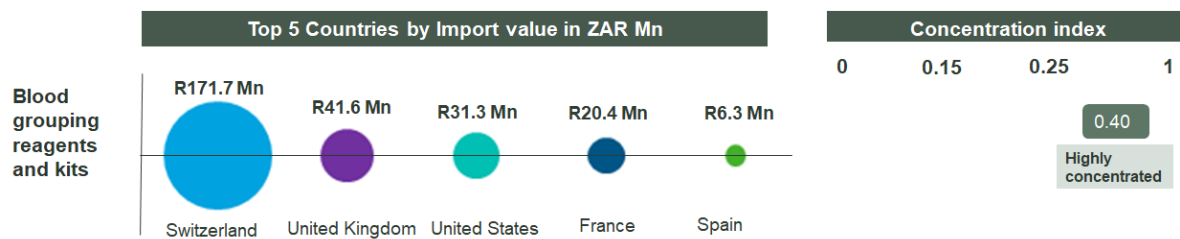


Blood Grouping Reagents and Kits

South Africa imported approximately R286.2 million worth of blood-grouping reagents and kits between 2021 and 2025, with imports nearly doubling from 2021 to 2025, reflecting a strong 18% CAGR.

Category	Total import value (2021-25)	CAGR
Blood grouping reagents and kits	R286.3 Mn	18%

South Africa's blood-grouping reagents and kits import market is highly concentrated, with an HHI of 0.40, indicating significant dependence on a limited number of supplier countries. Switzerland overwhelmingly dominates the market, accounting for 60% of total imports and recording strong growth of 51% CAGR, reinforcing its position as the country's primary source of blood-grouping diagnostics. The United Kingdom is the second-largest supplier with a 15% share, while the United States contributes 11% of imports. The top three suppliers (Switzerland, the United Kingdom, and the United States) account for approximately 86% of total imports, while the top five suppliers contribute about 95% of total import value. Overall, South Africa remains heavily reliant on imported blood-grouping reagents and kits, with a particularly strong dependence on Swiss suppliers.



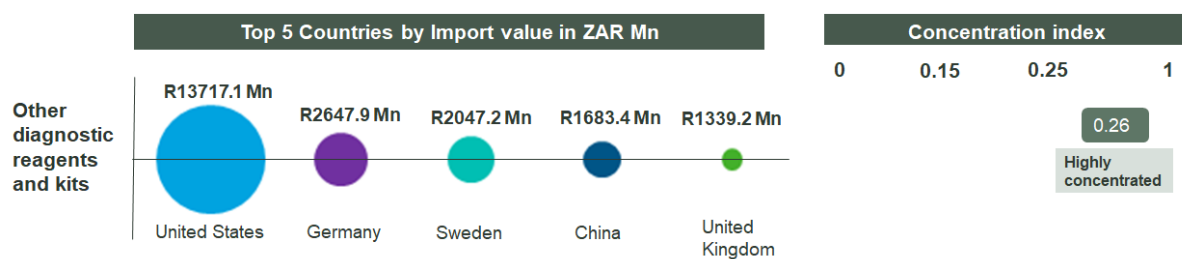
Other IVD reagents and test kits

South Africa imported approximately R23.6 billion worth of other in vitro diagnostic (IVD) reagents and test kits between 2021 and 2025, making it one of the largest medical technology categories in the healthcare sector. Imports remained relatively stable over the period, increasing marginally, resulting in a modest 1% CAGR. Despite limited growth, the consistently high import values underline the critical importance of IVD reagents in laboratory diagnostics, disease detection, screening, monitoring, and clinical decision-making across both public and private healthcare systems. Overall, the category represents a strategically important segment of the healthcare supply chain and highlights the country's continued dependence on imported diagnostic reagents and testing technologies.

Category	Total import value (2021-25)	CAGR
Other IVD reagents and test kits	R23681.1 Mn	1%

South Africa's other IVD reagents and test kits market is highly concentrated, with an HHI of 0.26, reflecting a meaningful dependence on a small number of global diagnostic suppliers. The United States dominates the market, accounting for 49% of

total imports between 2021 and 2025 and maintaining steady growth (2% CAGR), making it by far the most important supplier of diagnostic reagents and test kits. Germany ranks second with a 9% share and moderate growth (4% CAGR), followed by Sweden (7%), China (6%), and the United Kingdom (5%). Among the major suppliers, China recorded the strongest growth (+7% CAGR), increasing its presence in the market. The top five supplier countries account for approximately 76% of total imports, while the United States alone supplies nearly half of all imports, highlighting South Africa's significant reliance on US-based diagnostic manufacturers. Overall, while the supplier base remains reasonably diversified beyond the dominant US position, South Africa continues to rely heavily on imported diagnostic reagents and test kits, with moderate concentration risk and growing participation from Asian suppliers, particularly China.

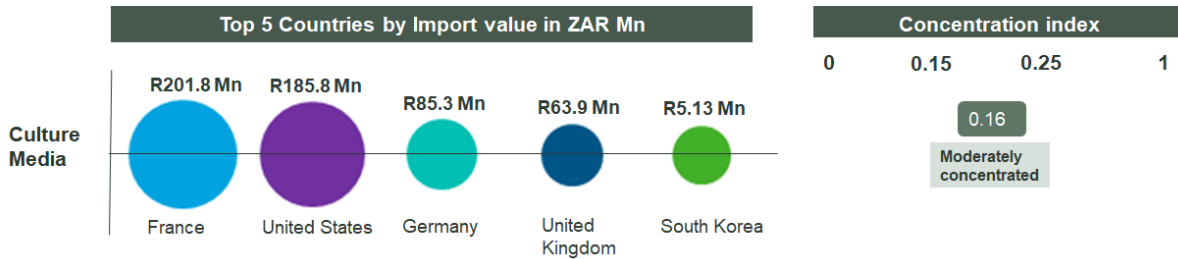


Culture media

South Africa imported approximately R756.9 million worth of culture media between 2021 and 2025, with imports declining, resulting in a -7% CAGR over the period. Culture media are essential laboratory products, highlighting the continued importance of microbiology and laboratory testing within South Africa's healthcare and research ecosystem. Nevertheless, the import volumes indicate sustained demand for diagnostic and research-related consumables and highlight South Africa's continued reliance on imported culture media.

Category	Total import value (2021-25)	CAGR
Culture media	R756.9 Mn	-7%

South Africa's culture media import market is relatively diversified, with a moderate HHI of 0.16, indicating limited supplier concentration and a balanced sourcing structure. France is the largest supplier, accounting for 27% of total imports and maintaining steady growth (6% CAGR), closely followed by the United States, which contributes 25% of imports despite experiencing a significant decline (-19% CAGR). The top three suppliers (France, United States, and Germany) account for approximately 63% of total imports, while the top five suppliers contribute nearly 79%, meaning more than five countries are required to reach the 80% threshold.

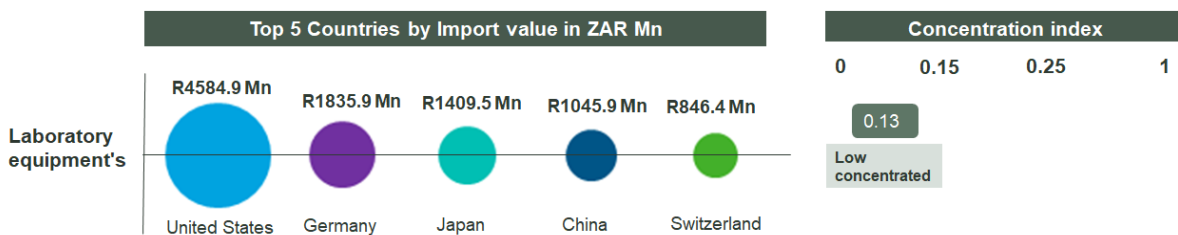


Laboratory equipment

South Africa imported approximately R15.2 billion worth of laboratory equipment between 2021 and 2025, making it one of the largest diagnostic and life sciences equipment categories in the healthcare sector, with a strong 11% CAGR.

Category	Total import value (2021-25)	CAGR
Laboratory equipment	R15181.7 Mn	11%

South Africa's laboratory equipment import market is relatively diversified, with a low HHI of 0.13, indicating limited supplier concentration and a resilient sourcing structure. The United States is the largest supplier, accounting for 30% of total imports between 2021 and 2025, followed by Germany (12%), Japan (9%), China (7%), and Switzerland (6%). Among the major suppliers, China recorded the strongest growth (+22% CAGR), highlighting its increasing competitiveness in the laboratory equipment segment. Overall, while South Africa remains highly dependent on imported laboratory equipment to support diagnostics, research, biotechnology, and testing activities, the low concentration level and balanced supplier mix reduce supply-chain risk and enhance resilience against disruptions from any single source country.



ANNEXURE 2: ANALYSIS FOR MEDTECH CATEGORIES - LOGIS DATA

Catheters and related

Catheters and related products accounted for approximately R287.9 million in LOGIS-recorded procurement between FY2022/23 and FY2025/26, representing approx. 2.7% of total MedTech expenditure. Despite its relatively modest share of overall procurement, the category recorded a very strong 80% CAGR, making it one of the

fastest-growing MedTech segments during the review period. Procurement increased significantly from R15.5 million in FY2022/23 to R90.7 million in FY2025/26.

The supplier landscape for catheters and related products appears relatively concentrated, with the top 10 suppliers accounting for approximately R175.62 million, representing around 61% of total category procurement. Teleflex Medical emerged as the leading supplier with procurement of R43.19 million, accounting for approximately 15% of total category spend, reflecting its strong position in vascular access, critical care, and interventional products. B. Braun Medical (R25.91 million) and DPR Pharmaceuticals (R23.03 million) followed as the second and third largest suppliers, while Marcus Medical (R20.15 million) and Endosurgical (R14.40 million) also maintained significant market shares. The supplier mix is characterised by the presence of both multinational MedTech companies and local distributors, indicating a competitive market structure. Notably, the top three suppliers accounted for approximately 32% of total procurement, while the top ten suppliers collectively represented about 61%, suggesting a moderate concentration level with a relatively broad supplier base beyond the leading players.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Teleflex Medical	R43.19	15%
B. Braun Medical	R25.91	9%
DPR Pharmaceuticals	R23.03	8%
Marcus Medical	R20.15	7%
Endosurgical	R14.40	5%
Adcock Ingram Critical Care	R11.52	4%
Vertice Healthcare	R11.51	4%
Baroque Medical	R8.64	3%
Medtronic Africa	R8.75	3%
Vascumed	R8.53	3%

A key inference from both the LOGIS procurement data and the transversal contract pricing data is that South Africa's catheter market appears to be predominantly import-led rather than manufacturing-led. While many suppliers participating in public tenders are South African entities, the vast majority function as distributors and importers rather than original manufacturers.

Tubes and cannulae

Tubes and cannulae procurement recorded through the LOGIS system totalled approximately R357.8 million between FY2022/23 and FY2025/26, accounting for approx. 3.3% of total MedTech expenditure. The category demonstrated exceptionally strong growth, increasing from R24.1 million in FY2022/23 to R130 million in

FY2025/26, equivalent to a robust 76% CAGR. Demand was primarily driven by intravenous cannulae, which accounted for 26% of total category expenditure (R93.0 million), followed by nasal cannulae (20%; R71.6 million), highlighting the importance of vascular access and respiratory support products within public healthcare facilities. Other major products included endotracheal tubes, feeding tubes, drainage tubes, surgical tubing, venous cannulae, tracheal tubes, and tracheostomy tubes and others.

The supplier landscape for tubes and cannulae is moderately concentrated, with Respiratory Care Africa emerging as the leading supplier, accounting for R67.9 million (19%). B. Braun Medical follows closely with R57.3 million (16%). Together, the two largest suppliers account for approximately 35% of total category spend, indicating a meaningful concentration among established suppliers. Other notable suppliers include Akacia Medical (5%), Tecmed (5%), Supra Healthcare Cape Town (4%), and Medtronic Africa (4%), while Endomed Medical and Surgical Supplies, Allenco Medical and Dental Supplies, Tiger Med, and Teleflex Medical each contributed between 2% and 3% of total expenditure. The supplier mix reflects a combination of multinational MedTech companies and local distributors, with several leading suppliers acting primarily as importers of globally manufactured products.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Respiratory Care Africa	R67.90	19%
B. Braun Medical	R57.30	16%
Akacia Medical	R18.10	5%
Tecmed	R17.70	5%
Supra Healthcare Cape Town	R14.60	4%
Medtronic Africa	R14.20	4%
Endomed Medical and Surgical Supplies	R10.90	3%
Allenco Medical and Dental Supplies	R10.50	3%
Tiger Med	R10.10	3%
Teleflex Medical	R6.69	2%

A key inference from both the LOGIS procurement data and the transversal contract pricing data is that South Africa's tubes and cannulae market appears to be predominantly import-led rather than manufacturing-led. While many suppliers participating in public tenders are South African entities, the vast majority function as distributors and importers rather than original manufacturers.

Assistive products

Assistive products represented a significant and rapidly expanding category within LOGIS-recorded MedTech procurement, with total expenditure reaching approximately R681.5 million between FY2022/23 and FY2025/26. Procurement increased substantially from R48.8 million in FY2022/23 to R250.3 million in FY2025/26, reflecting a strong 73% CAGR and highlighting growing investment in products that support mobility, hearing, vision, rehabilitation, and independent living. Demand was primarily driven by wheelchair parts and accessories, which accounted for R204.5 million (30%) of total assistive product procurement, followed by hearing aids (R129.5 million, 19%), crutches (R68.2 million, 10%), patient lift and transfer devices (R54.5 million, 8%), spectacles (R47.7 million, 7%), prostheses (R50.0 million, 7%), and walking frames (R30.1 million, 4%). Together, these categories accounted for approximately 85% of total assistive product expenditure, indicating that procurement is heavily concentrated in mobility aids, hearing solutions, and rehabilitation-related devices. The strong growth trajectory reflects increasing demand for disability support services, rehabilitation care, mobility assistance, hearing and vision correction, and long-term patient support, underscoring the growing importance of assistive technologies within South Africa's public healthcare system.

The top 10 suppliers accounts for approximately 65% of total category procurement, indicating that while a core group of suppliers dominates expenditure, a sizeable portion of procurement remains distributed across a broader supplier base. CE Mobility is the clear market leader, accounting for R143.1 million (21%) of total procurement, reflecting its strong position in mobility-related products. Batho Kopanang Distributors and Thokomala Mobility Services each contributed 7% of total expenditure, followed by Shonaquip (6%), a well-established provider of mobility solutions. The supplier mix also reflects the diversity of assistive product demand, with Carevision Eye Care (5%) supplying vision-related products, while Hear Tronix SA (5%) and I Hear 360 (3%) are prominent hearing-aid providers. Suppliers such as Maponya 911 Emergency Medical Services, High Care EMS, and Medproc contribute across mobility, patient-transfer, and rehabilitation segments.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
CE Mobility	R143.1	21%
Batho Kopanang Distributors	R49.0	7%
Thokomala Mobility Services	R46.2	7%
Shonaquip	R40.9	6%
Carevision Eye Care	R35.0	5%
Hear Tronix Sa	R33.2	5%
Maponya 911 Emergency Medical Services	R28.0	4%

High Care Ems	R26.4	4%
Medproc	R21.5	3%
I Hear 360	R19.7	3%

The wheelchair procurement market between FY2022/23 and FY2025/26, with CE Mobility accounting for approximately 69% of total procurement, making it the dominant supplier in the category. Shonaquip was the second-largest supplier with an 18% share, followed by Thokomala Mobility Services (6%), Medifoam (3%), and Timion (1%). Together, these five suppliers accounted for approximately 97% of total wheelchair procurement. Analysis of the RT233-2023 Wheelchairs Transversal Contract indicates that the South African public-sector wheelchair market is predominantly supplied through locally manufactured or locally assembled products. Leading wheelchair suppliers, including CE Mobility and Shonaquip, source the majority of their wheelchair ranges from South Africa. While imported products are present, particularly from Taiwan, the United Kingdom, the United States, Spain, Mexico, and the Netherlands, these are primarily concentrated in specialised wheelchair models, seating systems, and pressure-relief accessories. Overall, the contract data suggests a strong local manufacturing base for wheelchairs, with imports playing a complementary role in providing advanced and highly specialised mobility solutions.

The hearing aid market is highly concentrated and predominantly import-driven, with Batho Kopanang Distributors (36%), Hear Tronix SA (25%), I Hear 360 (17%), and Medifix Hearing Systems (5%) collectively accounting for approximately 83% of total procurement spend. While these companies are the leading suppliers, they primarily act as distributors of internationally manufactured hearing aids rather than local manufacturers. Transversal tender data shows that the products supplied originate mainly from Denmark, Switzerland, Austria, Sweden, Germany, the United States, Italy, and the United Kingdom. Although limited local manufacturing exists for certain accessories and consumables, there is little evidence of significant South African manufacturing capability for advanced digital hearing aids. Consequently, the market is characterised by a concentrated distributor base and high dependence on imported technology.

LOGIS data for crutches and walkers highlights that Thokomala Mobility Services (31%), Medproc (20%), Orthopaedic Textiles (9%), Dynamed Pharmaceuticals (8%), and Well-Care Medical Products (5%) account for approximately 73% of procurement spend. Analysis of the RT40-2024 transversal contract indicates that the category remains largely import-driven, with most crutches, walkers, walking sticks, ferrules, and mobility accessories sourced from China and Taiwan through local distributors and medical supply companies. Although local manufacturers such as Orthopaedic Textiles provide a range of South African-manufactured mobility products, domestic production represents a relatively small portion of the overall market. Consequently, the category can be characterised as predominantly import-dependent.

The prosthetics market appears moderately fragmented relative to hearing aids and slightly less concentrated than mobility aids, with Xpros International (23%) and MyOrtho Solutions (16%) as the two largest suppliers, followed by MBES Medical Supply Investment (7%), Ossur SA (7%), Prosthetic Suppliers (6%), Medroma (4%), Orthopaedic Suppliers (4%), Vertice Healthcare (4%), and Ortholam (3%). The top nine suppliers collectively account for approximately 74% of total procurement spend, indicating a competitive market with several specialist providers rather than dominance by a few firms. The category remains significantly dependent on imported prosthetic technologies and components.

Collection device

The Collection Devices category recorded strong growth, increasing from ZAR 49.0 million in FY2022/23 to ZAR 103.6 million in FY2025/26, generating cumulative expenditure of ZAR 297.1 million and achieving a CAGR of 28% over the review period. Spend is highly concentrated in ostomy-related products, with Bag, ostomy accounting for ZAR 197.4 million (66%) of total expenditure, followed by Bag, drainage, urine (8%) and Bag, stoma/ostomy, adhesive (6%). Together, ostomy pouches, urostomy products, and associated barriers and flanges represent approximately 80% of category spend, highlighting the significant demand for long-term stoma care products. Supplier expenditure is similarly concentrated, with OMS Medical (33%), Hartmann-Vitamed (19%), and Coloplast (10%) accounting for approximately 62% of total category spend, while the top ten suppliers collectively represent around 84% of expenditure. The prominence of suppliers such as OMS medical, Hartmann Vitamed, Coloplast, and others together with extensive procurement of branded ostomy, urostomy, and stoma-care products, indicates that the category is heavily dependent on imported technologies and multinational manufacturers.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
OMS Medical	R98.0	33%
Hartmann-Vitamed	R57.0	19%
Coloplast	R29.5	10%
Adcock Ingram Critical Care	R12.5	4%
Sinapi Manufacturing	R11.8	4%
Access Medical	R10.8	3%
B. Braun Medical	R9.8	3%
Grobir Medical Suppliers	R9.1	3%
Akacia Medical	R7.0	2%

I Hear 360

R6.8

2%

The transversal contract data indicates that while the broader Collection Devices category is largely import dependent, there is evidence of a small but established local manufacturing base in South Africa, primarily focused on drainage consumables, tubing, chest drainage systems and wound drainage products. Local manufacturers and brands identified include Sinapi Manufacturing (chest drainage systems and Heimlich valves), Technomed (wound drainage sheets, pencil drains and tubing), U-Life/Medi-Core Technologies (Yankauer suction tubes and silicone tubing), and Akacia Medical (pencil drains). These locally manufactured products are concentrated in lower-value drainage and tubing segments rather than the high-spend areas of the category. However, the category remains heavily dependent on imported products for the largest expenditure segments. This is particularly evident in ostomy, urostomy and stoma-care products, which account for approximately 72% of total category spend when combining Bag, ostomy (66%) and Bag, stoma/ostomy adhesive (6%). These products are supplied predominantly by multinational manufacturers such as Coloplast, Hollister and ConvaTec, with local companies acting primarily as distributors rather than manufacturers. The supplier profile further supports this view, with OMS Medical (33%), Hartmann-Vitamed (19%) and Coloplast (10%) accounting for over 60% of total category expenditure, indicating reliance on imported branded technologies.

The country-of-origin analysis also shows significant sourcing from China, India, Germany, France, the United States and the United Kingdom, particularly for chest drainage systems, drainage catheters, wound drainage systems, suction consumables and specialised collection devices. While opportunities exist to expand local manufacturing in drainage and tubing products, substitution opportunities for advanced ostomy and urostomy products are currently limited due to proprietary technologies, specialised materials and established international brands.

Sutures

The Sutures category experienced exceptional growth over the review period, increasing from ZAR 4.5 million in FY2022/23 to ZAR 26.5 million in FY2025/26, with cumulative expenditure of ZAR 76.7 million and an impressive CAGR of 81%. Supplier expenditure is relatively concentrated, with Akacia Medical accounting for 26% (ZAR 20.2 million) of total spend, followed by Johnson & Johnson (17%), Synthecon Sutures Manufacturing (14%), Gabler Surgical (8%), B. Braun Medical (6%), and Vertice Healthcare (5%). The top six suppliers collectively account for approximately 76% of category expenditure, indicating a concentrated but competitive market

Supplier	Total procurement value 2022/23 to 2025/26 (In R mn)	Share
Akacia Medical	R20.2	26%

Johnson & Johnson	R12.9	17%
Synthecon Sutures Manufacturing	R10.5	14%
Gabler Surgical	R6.2	8%
B. Braun Medical	R4.9	6%
Vertice Healthcare	R4.1	5%
Grobir Medical Suppliers	R2.6	3%
Baroque Medical	R0.9	1%
Farmervet	R0.8	1%
Biologica Pharmaceuticals	R0.8	1%

Based on the transversal contract data, the category demonstrates a significantly stronger local manufacturing presence than many other medical consumable categories. Analysis of the Country of Origin and Manufacturer fields indicates that the vast majority of products are manufactured in South Africa, with local manufacturers including Akacia Medical, Synthecon Sutures Manufacturing SA CC, and Gabler Medical (Pty) Ltd (Scimitar brand). While international companies such as Johnson & Johnson (17%), B. Braun Medical (6%), and other global suppliers continue to play an important role in specialised and premium suture technologies, the RT302 contract demonstrates that South African manufacturers are capable of producing a broad spectrum of surgical sutures.

Imaging / nuclear medicine equipment

The Imaging / Nuclear Medicine Equipment category has demonstrated exceptional growth, with expenditure increasing from 83.0 million in FY2022-23 to 472.8 million in FY2025-26, resulting in a cumulative spend of 1.13 billion and a CAGR of 79%. Growth was driven primarily by investments in high-value diagnostic imaging technologies, with the top 10 products contributing approximately 85% of total category spend. The largest spend category was General-Purpose Digital X-ray Systems at 239.7 million (21%), followed by CT Scanning Systems at 195.8 million (17%). Significant investments were also made in Digital X-ray Detectors (91.3 million, 8%), Mobile Digital C-arm Systems (89.2 million, 8%), PET/CT Systems (73.6 million, 6%), Bucky Stands (69.7 million, 6%), Mobile Digital X-ray Systems (67.6 million, 6%), MRI Systems (52.8 million, 5%), Gamma Camera/SPECT Systems (52.3 million, 5%), and Portable Digital X-ray Systems (36.7 million, 3%).

From a supplier perspective, expenditure is highly concentrated among a relatively small number of predominantly international OEMs and their local distribution partners. Siemens accounted for 237.3 million (21%) of total spend, followed by Tecmed at 209.1 million (18%), Lomaen Medical at 148.4 million (13%), AXIM at 116.5 million (10%), and Mamello Clinical Solutions at 97.1 million (9%), with the top five suppliers collectively representing approximately 71% of total category expenditure. Additional

key suppliers included Philips (5%), East Cape X-Ray (5%), Africa X-Ray Industrial and Medical (5%), DRGEM Africa Corporation (2%), and Folivex (2%). The supplier highlights the highly imported nature of the imaging market, where advanced modalities such as CT, MRI, PET/CT, SPECT/Gamma Cameras, digital radiography systems, detectors, and C-arms are largely sourced from global manufacturers and supported through local distributors and service providers.

Supplier	Total procurement value 2022/23 to 2025/26 (In R mn)	Share
Siemens	R237.34	21%
Tecmed	R209.12	18%
Lomaen Medical	R148.37	13%
Axim	R116.45	10%
Mamello Clinical Solutions	R97.10	9%
Philips	R60.42	5%
East Cape X-Ray	R56.27	5%
Africa X-Ray Industrial And Medical	R54.91	5%
DRGEM Africa Corporation	R27.17	2%
Folivex	R22.99	2%

Despite this reliance on imported equipment, South Africa has a notable local imaging success story in the form of the Lodox full-body digital X-ray system, a technology developed and manufactured locally that has gained international recognition for its rapid full-body imaging capability. The presence of Lodox demonstrates that while the broader imaging market remains import-driven, there is domestic capability for specialized imaging innovation and manufacturing.

Dressings, gauzes, bandages, pads

The Dressings, Gauzes, Bandages, and Pads category has experienced substantial and sustained growth, increasing from 45.3 million in FY2022-23 to 304.5 million in FY2025-26, resulting in a cumulative expenditure of 857.3 million and a CAGR of 89%. The expenditure profile is heavily concentrated in Pads, Female Sanitary, which accounted for 274.3 million (32%) of total spend, Other major spend areas included Gauze Swabs (123.5 million, 14%), Antimicrobial Gauze Strips (115.8 million, 14%), Absorbent Pads (96.5 million, 11%), and Transparent Film Dressings (92.9 million, 11%), together representing approximately 82% of total category expenditure. Additional spend on Surgical Dressing Kits (37.1 million, 4%), Paraffin Gauze Dressings (19.4 million, 2%), Adhesive Plasters (19.2 million, 2%), Adhesive Dressing Strips (16.8 million, 2%), and Antiseptic Gauzes (15.8 million, 2%) further

demonstrates the breadth of products required to support routine wound care, surgical procedures, infection prevention, and patient care activities.

From a supplier perspective, the category is relatively fragmented compared with capital equipment categories, although spending remains concentrated among a group of established manufacturers and distributors. Akacia Medical was the largest supplier with 80.5 million (9%) of total spend, closely followed by National Pride (79.8 million, 9%), BMS Medical Supplies (76.7 million, 9%), and BSN Medical (75.9 million, 9%). Other key suppliers included OMS Medical (49.8 million, 6%), Lion Match Products (38.8 million, 4%), Logan Medical & Surgical (33.4 million, 4%), Augustine Medical SA (32.6 million, 4%), Vertice Healthcare (28.9 million, 3%), and Quality Medical Supplies (18.0 million, 3%). The top ten suppliers collectively account for approximately 60% of total category spend, indicating a competitive supplier market with multiple participants supporting supply continuity.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Akacia Medical	R80.5	9%
National Pride	R79.8	9%
BMS Medical Supplies	R76.7	9%
BSN Medical	R75.9	9%
OMS Medical	R49.8	6%
Lion Match Products	R38.8	4%
Logan Medical & Surgical	R33.4	4%
Augustine Medical SA	R32.6	4%
Vertice Healthcare	R28.9	3%
Quality Medical Supplies	R18.0	3%

Analysis of transversal tender data highlights that dressings, gauzes, bandages and pads market is far less import-dependent than other medical devices, but import reliance increases significantly as product complexity rises. Commodity products such as gauze, cotton, paraffin dressings, and standard wound dressings are largely sourced locally, whereas advanced wound care products including antimicrobial, silver, alginate, hydrocolloid, honey-based, foam, collagen, and NPWT dressings remain heavily dependent on imported technologies from China, the UK, Germany, Finland, Sweden, the US, and Egypt. Overall, the category offers substantial opportunities for local manufacturers to expand into advanced wound care segments and reduce import reliance, particularly in silver, hydrofiber, alginate, and antimicrobial dressing technologies.

Endoscopes and related device

The Endoscopes and Related Devices category recorded a total expenditure of 201.3 million over the review period, growing at a 13% CAGR, reflecting sustained investment in minimally invasive diagnostic and therapeutic services. Spending is heavily concentrated in Endoscopy Systems, which accounted for 167.1 million (83%) of total expenditure. Video-colonoscopes (5%), Bronchoscopes (3%), and Rigid Cystoscopes (3%) were the next largest categories, together contributing 11% of total spend. Overall, the category reflects a clear focus on advanced video-assisted endoscopy, platform modernisation, and expansion of minimally invasive clinical services, with procurement concentrated on high-value endoscopy systems that support multiple specialties and procedures.

The supplier base is highly concentrated, with Karl Storz Endoscopy (South Africa) (40%) and Tecmed (22%) together accounting for 62% of total expenditure, while the top three suppliers, including Grobir Medical Suppliers (11%), represent 73% of spend. This concentration highlights a strong reliance on a limited number of suppliers and underscores the category's dependence on imported endoscopy platforms, imaging systems, scopes, and specialised accessories. The remaining spend is distributed across suppliers such as Surgical Innovations, Vertice Healthcare, Boston Scientific SA, B. Braun Medical, SSEM Mthembu Medical, Marcus Medical, and Johnson & Johnson Medical, which primarily support niche requirements through specialised endoscopy devices, therapeutic products, and procedural consumables.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Karl Storz Endoscopy (South Africa)	R80.5	40%
Tecmed	R44.3	22%
Grobir Medical Suppliers	R22.1	11%
Surgical Innovations	R8.0	4%
Vertice Healthcare	R6.0	3%
Boston Scientific SA	R4.8	2%
B. Braun Medical	R4.4	2%
SSEM Mthembu Medical	R4.1	2%
Marcus Medical	R3.7	2%
Johnson & Johnson Medical	R3.5	2%

Evidence, including the transversal contract, highlights that the Endoscopes and Related Devices category is highly import-dependent, with virtually all major endoscopy platforms, scopes, imaging systems, and washer-disinfectors sourced from international manufacturers. The highest-spend subcategories such as

Endoscopy Systems, Video Colonoscopes, Bronchoscopes, Cystoscopes, Video Laryngoscopes, and Flexible Laryngoscopes rely heavily on technology originating from Germany, Japan, Italy, and China, with no evidence of local manufacturing. Local companies act primarily as distributors and service providers rather than OEM manufacturers. Additionally, the dependency extends beyond capital equipment to replacement scopes, processors, valves, cables, irrigation systems, leak testers, cleaning accessories, and washer-disinfector consumables, indicating ongoing reliance on imported spare parts and consumables throughout the equipment lifecycle.

Syringes and Needles

The Syringes and Needles category recorded a total spend of R188.83 million between FY2022-23 and FY2025-26, growing from R14.34 million in FY2022-23 to R62.95 million in FY2025-26, representing a strong 64% CAGR. The category experienced a significant surge in FY2023-24, with spend increasing by nearly 297% to R56.89 million, followed by a slight normalisation in FY2024-25 (R54.64 million, down 4%), before recovering to a peak of R62.95 million in FY2025-26. Product spending was dominated by hypodermic syringes (35%), followed by hypodermic needles (16%), insulin syringes (R26.00 million; 14%), biopsy needles (R16.63 million; 9%) and spinal needles (6%), together accounting for approximately 80% of total category spend. Supplier spend was led by Becton Dickinson with R30.57 million (16%), followed by Embecta South Africa at R12.38 million (7%), Medi-Core Technologies at R9.11 million (5%), Isigidi Trading 95 at R8.77 million (5%), and Promed Technologies at R7.69 million (4%). Collectively, these top five suppliers contributed approximately 37% of total category expenditure, indicating a low-concentration supplier base with Becton Dickinson maintaining a clear leadership position in the category.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Becton Dickinson	R30.6	16%
Embecta South Africa	R12.4	7%
Medi-Core Technologies	R9.1	5%
Isigidi Trading 95	R8.8	5%
Promed Technologies	R7.7	4%
Creatori Health	R6.5	3%
Endomed Medical & Surgical Supp	R6.4	3%
Bard Medical SA	R6.2	3%
Diverse Pharmaceuticals	R6.1	3%
Supra Healthcare KZN	R6.0	3%

Based on the supplier spend analysis, the LOGIS product mix, and the RT284 transversal contract country-of-origin data, the Syringes and Needles category appears to be highly import dependent, with the majority of products sourced from China, while a smaller portion is sourced from Europe (primarily Becton Dickinson products manufactured in Spain/France as listed in the contract). The RT284 contract shows that key suppliers such as Medi-Core Technologies (ULIFE), Biocor Hospital Supplies (SYR-CARE/NDL-CARE), Supra Healthcare (Avacare), and Unitrade/Webest predominantly supply products of Chinese origin, while Becton Dickinson, the largest supplier in the category with R30.57 million (16%) spend, supplies hypodermic needles, syringes, BCG syringes and related products manufactured in Europe. Isigidi Trading 95 supplies products largely identified as China/South Africa or Chinese origin, indicating local distribution rather than local manufacturing. Embecta South Africa (7% spend share) operates locally but its insulin syringes and diabetes-related devices are generally sourced from Embecta's global manufacturing network rather than produced domestically. Mapping this against the LOGIS spend profile, the largest products by spend are predominantly supplied by importers and distributors rather than South African manufacturers. Therefore, although several leading suppliers are South African-registered companies, the category itself is estimated to be heavily import-reliant, with China serving as the primary manufacturing source and Europe contributing through multinational suppliers such as Becton Dickinson.

Respiratory care accessories

The respiratory accessories category has demonstrated exceptional growth, increasing from R15.4 million in 2022-23 to R108.2 million in 2025-26, resulting in a cumulative expenditure of R298.6 million and a 91% CAGR over the period. Product-level analysis shows that procurement is heavily concentrated in breathing circuit and oxygen delivery products, led by ventilator breathing circuits (30% of total spend) and masks (22%), the latter comprising a range of products such as oxygen masks, Venturi masks and related oxygen delivery interfaces. Other significant categories include high-flow breathing circuits (6%), CPAP bonnets (6%), CPAP breathing circuits (6%), and anaesthesia breathing circuits (5%), highlighting the growing utilisation of oxygen therapy, ventilatory support, neonatal CPAP and anaesthesia services across healthcare facilities.

Supplier concentration analysis further indicates a relatively consolidated market, with Respiratory Care Africa dominating the category with R113.5 million (38%) of total spend, followed by SSEM Mthembu Medical at R53.7 million (18%). Together, these two suppliers account for 56% of total respiratory accessories expenditure, demonstrating significant market concentration. Other notable suppliers include Mbuso Medical Supplies (4%), Teleflex Medical (4%), Intersurgical (4%), Class Three Medical Solution (3%), Dräger South Africa (2%), Promed Technologies (2%), and PTA Agencies (2%). The combination of strong market growth, high concentration in breathing circuits and mask-related products, and reliance on a limited number of

suppliers suggests substantial opportunities for localisation and import substitution, particularly in high-volume consumables such as oxygen masks, Venturi masks, ventilator circuits, CPAP circuits and other respiratory therapy accessories.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Respiratory Care Africa	R113.5	38%
SSEM Mthembu Medical	R53.7	18%
Mbuso Medical Supplies	R12.8	4%
Teleflex Medical	R11.9	4%
Intersurgical	R11.4	4%
Class Three Medical Solution	R8.9	3%
Dräger South Africa	R6.8	2%
Promed Technologies	R6.2	2%
PTA Agencies	R5.5	2%
Phoenix Neomed	R3.5	1%

Respiratory accessories procured by the state are almost entirely imported. Nearly two thirds of the RT13-2024 contract originate in China, with the remainder drawn largely from Lithuania, India, the United Kingdom, Ireland, Turkey, Mexico and Germany. South African origin appears only marginally, accounting for a negligible share of the contract. The supplier base reflects this structure directly. The largest participants, Supra Healthcare, Diverse Pharmaceutical, Stat-Tiakeni Medical, Dynamed Pharmaceuticals, SSEM Mthembu Medical, Allenco Medical & Dental, Biocor Hospital Supplies and Lechoba Medical, are importers and distributors sourcing predominantly Chinese product under their own or licensed house brands, with the underlying manufacture concentrated in a relatively small group of Chinese original equipment manufacturers. A second and distinct tier comprises the local subsidiaries of multinational manufacturers, principally Intersurgical, Teleflex and Dräger, whose supply originates from group facilities in Lithuania, Ireland and Germany respectively.

In Vitro Diagnostics and laboratory equipment

The IVD category demonstrated strong and sustained growth over the analysis period, with expenditure increasing from R48.3 million in 2022/23 to R97.5 million in 2025/26, generating a cumulative spend of R353.6 million and a CAGR of 26%. Expenditure is highly concentrated in Clinical Chemistry Rapid Tests & Point of Care, which accounts for 50% (R176.8 million) of total spend, followed by Haematology Reagents at 29% (R102.5 million), meaning that nearly 79% of all IVD expenditure is directed towards routine diagnostic and point-of-care testing services. The supplier landscape is similarly concentrated, with Promed (23%), Hemocue SA (12%), and Tara Healthcare

(8%) collectively accounting for approximately 43% of total category expenditure, while the top ten suppliers contribute roughly 75% of total spend. This concentration indicates a mature but supplier-dependent market where a limited number of vendors dominate critical diagnostic testing categories. The combination of strong market growth, heavy reliance on rapid and point-of-care testing, and significant supplier concentration highlights the strategic importance of IVD procurement and underscores the need for supply chain resilience, supplier diversification, and ongoing monitoring of key vendors to mitigate supply risks and ensure continuity of diagnostic services.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Promed	R81.3	23%
Hemocue SA	R42.4	12%
Tara Healthcare	R28.3	8%

While these entities operate within South Africa, most are distributors or representatives of multinational diagnostic manufacturers rather than local manufacturers. Coupled with the dominance of categories such as Clinical Chemistry Rapid Tests & Point of Care (50%) and Haematology Reagents (29%), which typically rely on proprietary analysers, reagents, and consumables sourced from global manufacturers, the evidence suggests that South Africa's IVD market is largely dependent on imported diagnostic technologies. The concentration of spend among a limited number of suppliers also indicates potential supply chain vulnerability, as access to critical diagnostic testing is likely linked to the availability of imported reagents, kits, and instrumentation.

Infection prevention and control

Expenditure on infection prevention and control recorded in LOGIS totalled R453.6 million over the four years to 2025-26, rising from R44.2 million in 2022-23 to R118.6 million in 2023-24 and R145.4 million in 2024-25, before remaining essentially unchanged at R145.4 million in 2025-26. Within this expenditure, the category is highly concentrated, with six products accounting for 92% of the total. Examination gloves represent 37% and surgical gloves a further 31%, such that gloves alone account for R308.9 million, or slightly over two thirds of all infection prevention and control spend, followed by surgical drapes at 10%, sanitary wipes at 8%, masks at 3% and comfort packs at 3%.

Supplier concentration mirrors this pattern, with the ten largest suppliers accounting for approximately 67% of expenditure. Medtex SA alone represents 38% of the category, followed by Promed Technologies at 10%, Logan Medical and Surgical at 6% and Evergreen Latex at 3%, with the remaining suppliers each accounting for between one and two per cent.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Medtex SA	R171.9	38%
Promed Technologies	R45.9	10%
Logan Medical & Surgical	R26.2	6%
Evergreen Latex	R15.7	3%
PN Medical	R10.5	2%
Bfect (Pty) Ltd	R9.1	2%
Madeph Technical Services	R6.9	2%
Medical Plant Africa	R6.6	1%
Regen Technical Institute	R6.2	1%
TLG Trading	R6.1	1%

Analysis of the transversal contract highlights that gloves represent a strong existing localisation position, and the one in which local manufacture is already established and competing directly against imported product on identical specifications, with slightly over half the contract supplied from South African origin through two manufacturers, Medtex SA and Evergreen Latex. The split between the two glove types is the more revealing finding. Examination gloves are supplied predominantly from Malaysia, Indonesia and China, through importers led by Promed Technologies, Ikhaka Medical and SA Health Protecting Services, with local manufacturers holding only a minority position. Surgical gloves, by contrast, are supplied overwhelmingly from South African origin, with Medtex SA holding the large majority of the range and Evergreen Latex the latex lines, and imported product confined to a small number of specialised items. Domestic lead times of fourteen to twenty-one days exceed the leading importer's seven, indicating that stockholding and scheduling rather than manufacturing capability constrain local supply.

Medical furniture

The medical furniture category demonstrated exceptional growth over the review period, with expenditure increasing from R23.8 million in 2022/23 to R190.2 million in 2025/26, resulting in total spend of R382.5 million and a CAGR of 100%. Expenditure is dominated by Medical Beds (51%), encompassing ward beds, ICU beds, bariatric beds, maternity and delivery beds, paediatric cots, psychiatric beds, examination beds, stretchers, as well as related mattresses, accessories, repairs and replacement components. Trolleys (13%) represent the second-largest category and include both routine clinical trolleys and emergency/resuscitation trolleys that support patient care delivery, clinical workflows and emergency response activities. Medical Tables (12%), comprising operating theatre, orthopaedic, cardiac, overbed, Mayo, X-ray and examination tables, form the third-largest expenditure area. Additional spend is

concentrated in Carts (5%), which primarily support hospital logistics through mobile storage, medication, sterile supply, linen, procedure and transportation carts, and Medical Mattresses (5%). Supplier concentration is notably high, with Arjo Huntleigh South Africa accounting for 46% (R175.2 million) of total category expenditure, significantly ahead of the next largest suppliers, each holding between 2% and 5% share. This indicates a market strongly influenced by a single major supplier, while procurement remains focused on expanding inpatient capacity, strengthening critical care and emergency services, and modernising healthcare infrastructure and operational support systems across healthcare facilities.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Arjo Huntleigh South Africa	R175.2	46%
Kwa-Dube Medical	R17.7	5%
Hospi-Furn	R17.2	4%
Medhold Medical	R14.2	4%
Class Three Medical Solution	R14.0	4%
Millners Dental Suppliers	R12.5	3%
Respiratory Care Africa	R12.4	3%
Stieglmeyer Africa	R10.6	3%
Bioclin Solutions	R10.0	3%
Hospital Equipment Manufacturers	R8.8	2%

The RT24-2021 Hospital Furniture transversal contract indicates that South Africa possesses a well-established local manufacturing capability across most medical furniture segments, with approximately two thirds of contracted lines manufactured locally and the great majority of these declaring one hundred per cent local content. Domestic production is strongest in fabricated steel products, including trolleys, drip stands, stools, cabinets, lockers and overbed tables, which are almost entirely locally supplied, and extends to mechanically operated ward beds, examination couches, bassinets and mattresses. Local manufacturers such as New Horizon Metals, Hospital Equipment Manufacturers, Hospi-Furn, Gabler Medical Devices and Nomageba Medical feature prominently throughout the contract, with Arjo Huntleigh South Africa and Medhold Medical supplying a combination of locally manufactured and imported product. Import dependence is concentrated in specialised and technology-intensive furniture, principally advanced ICU beds, multifunction electric beds and height-adjustable examination couches, sourced from China, Poland, Germany, India and the United Kingdom. The determining factor is not the furniture category itself but the presence of electrical actuation within it, as demonstrated by hospital beds, where mechanical configurations are locally produced while every electrically actuated variant is imported at unit prices ranging from approximately R35,000 to R247,000.

Notably, and in contrast to consumable categories, local manufacture in this segment competes on cost rather than despite it, being cheaper than the imported equivalent in the majority of directly comparable items and offering shorter standard delivery periods. Overall, the medical furniture category demonstrates low-to-moderate import dependency, with the majority of standard ward furniture requirements supported by local manufacturing capability, and residual import reliance confined to a narrow and technically identifiable set of powered products.

Medical equipment

The medical equipment category generated total expenditure of approximately R1.31 billion over the review period, increasing from R156.8 million in 2022/23 to R230.2 million in 2025/26, with expenditure peaking at R539.6 million in 2023/24, resulting in a CAGR of 14%. Spending is concentrated in a relatively small number of high-value equipment categories, led by Ventilators (21%), followed by Infant Incubators (10%) and Anaesthesia Systems (9%). Respiratory and critical care technologies dominate the category, with CPAP Systems (7%), Radiant Warmers (7%), Suction Apparatus (3%) and Nebulisers (1%) accounting for a significant share of expenditure. Other notable categories include Examination Lamps (5%), Lancets (3%), Haemodialysis Machines (2%), Medical Stretchers and Surgical Handpieces (2%). The supplier landscape is moderately concentrated, with Class Three Medical Solution (13%), Respiratory Care Africa (12%), and Ecomed Medical (10%) collectively accounting for approximately 35% of total expenditure, while the top ten suppliers contribute around 68% of category spend. The presence of global medical technology companies and specialised distributors such as Dräger South Africa, Medtronic Africa, Maquet Southern Africa and B. Braun Medical further indicates a strong reliance on internationally manufactured technologies. Overall, the expenditure profile reflects significant investment in critical care, neonatal care, respiratory support, surgical services and specialised medical technologies, suggesting that South Africa's medical equipment market remains highly dependent on imported, technology-intensive devices supplied through local distributors and multinational manufacturers.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Class Three Medical Solution	R171.6	13%
Respiratory Care Africa	R154.5	12%
Ecomed Medical	R125.8	10%
SSEM Mthembu Medical	R97.9	7%
Medhold Medical	R97.7	7%
Dräger South Africa	R83.5	6%
Mbuso Medical Supplies	R76.3	6%
Medtronic Africa	R42.8	3%

Maquet Southern Africa	R29.8	2%
BEM Medical (Pty) Ltd	R28.5	2%

The RT2-2021 medical equipment transversal contract demonstrates near-total import dependence. Approximately three per cent of supplier offers declare South African origin, with the remainder sourced principally from China, Germany, the United States, Switzerland, Japan and Korea. Domestic participation is confined to refrigeration cabinets, comprising vaccine fridges, medicine fridges and fluid warmer cabinets, together with a wall-mounted suction unit and a portable obstetric vacuum extractor. No item incorporating sensing, software-controlled actuation or regulated measurement is domestically produced. The import channel is itself twofold: commodity clinical equipment in anaesthesia, ventilation, paediatric and obstetric categories originates predominantly in China, while advanced capital equipment in neurosurgery, ophthalmology and patient monitoring originates in Germany, the United States, Switzerland and Japan. The supplier base divides correspondingly between the local subsidiaries of international manufacturers, including Dräger, Philips, Carl Zeiss, Getinge, Medtronic and Karl Storz, and South African distributors carrying imported brands, with neither group undertaking local manufacture. Two structural features compound the dependence. Each item is contracted with a two-year warranty and a five-year post-warranty comprehensive maintenance schedule, binding the purchaser to the original manufacturer for a seven-year lifecycle extending well beyond the point of acquisition. And competitive participation is limited, with approximately thirty per cent of items attracting only a single offer and typical lead times of six to fourteen weeks. Medical equipment therefore represents the category in which import dependence is deepest, least contestable in the near term, and most closely tied to technological capability rather than to cost structure. The supplier base for medical equipment comprises two distinct models, neither of which involves local manufacture. The first consists of the local subsidiaries of foreign original equipment manufacturers, principally Dräger South Africa, B. Braun Medical, Medtronic Africa and Maquet Southern Africa, whose contracted product carries a single unmixed country of origin, predominantly Germany, the United States and Sweden, and whose value is concentrated in a small number of high-priced items. The second consists of South African distributors holding multi-origin portfolios assembled under agency agreements, including Medhold Medical, SSEM Mthembu Medical, Ecomed Medical, Respiratory Care Africa, Class Three Medical Solution and Mbuso Medical Supplies, several of which are almost entirely Chinese-sourced while others span five to ten countries of supply.

Cleaning / Disinfection / Sterilisation Equipment

The Cleaning / Disinfection / Sterilisation Equipment category experienced strong growth over the review period, increasing from R4.5 million in 2022/23 to R19.0 million in 2025/26, with expenditure peaking at R54.9 million in 2024/25. Total spend reached R94.6 million, resulting in a robust CAGR of 62%, reflecting increased investment in

infection prevention, sterile processing infrastructure, and healthcare compliance requirements. Expenditure is highly concentrated in Sterilisers (47%), followed by Sterilisation Wrappers (24%), Sterilisation Bags (13%), and Washer/Disinfectors (5%), with these four sub-categories accounting for approximately 89% of total category spend. Supplier spending is similarly concentrated, with Medi-Clave (36%; R33.8 million) and Safmed (21%; R20.1 million) together accounting for 57% of total expenditure, followed by Logan Medical & Surgical (10%; R9.0 million). Other notable suppliers include SSEM Mthembu Medical (4%), Surgi Plus Medical (2%), Marcus Medical (2%), Medhold Medical (2%), B. Braun Medical (2%), Tsingtsing Trading (2%), and Access Medical (1%).

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Medi-Clave	R33.8	36%
Safmed (Pty) Ltd	R20.1	21%
Logan Medical & Surgical	R9.0	10%
SSEM Mthembu Medical	R4.2	4%
Surgi Plus Medical	R2.0	2%
Marcus Medical	R2.0	2%
Medhold Medical	R1.7	2%
B. Braun Medical	R1.5	2%
Tsingtsing Trading	R1.4	2%
Access Medical	R1.1	1%

Local manufacturing is established in converted paper and nonwoven consumables, comprising sterilisation wraps, crepe paper, tubing, reels, bags and documentation envelopes, which account for the majority of locally originated supply and are manufactured under established South African brands including Steriguard, Steriflex, Ecoster, Zeta and Steri Crepe through converters such as Assegai Healthcare, Unitrade, Logan Medical and Surgical and Vital Life Medical Distributors. Within the same consumable range, however, precision formed and instrumented items are wholly imported, encompassing the entirety of instrument cleaning brushes in all configurations, colour code and masking tapes, chemical and biological indicators, labelling devices and their tracking labels, and low temperature hydrogen peroxide cassettes. This inversion becomes absolute in equipment, where autoclaves, ultrasonic cleaners, endoscope washers, heat sealing machines and low temperature plasma sterilisers, priced from approximately R56,000 to R1.65 million, are entirely imported from China, Taiwan, Italy, Germany, Mexico, the United Kingdom and the Netherlands, with no South African origin recorded at any price point. The supplier base reflects this division consistently, comprising domestic converters at the consumable end and the local subsidiaries of international manufacturers together

with South African distributors holding agency portfolios at the equipment end, the latter undertaking no manufacture.

Implantable devices

The Implantable Devices category demonstrated strong and sustained growth over the review period, with expenditure increasing from R56.9 million in 2022/23 to R323.7 million in 2025/26, resulting in cumulative spend of R791.4 million and a substantial CAGR of 66%. Spending is heavily concentrated in orthopaedic and trauma-related implants, led by Internal Bone Fixation Plates (27%; R213.8 million), Orthopaedic Joint Prostheses (16%; R127.7 million), Internal Bone Fixation Screws (16%; R124.9 million), and Orbital Implants (15%; R118.8 million), which together account for approximately 74% of total implantable device expenditure. Other notable categories include Sub-dermal Implants (3%; R23.5 million), Stents (3%; R21.7 million), Cochlear Implant Systems (3%; R20.7 million), Non-absorbable Surgical Mesh (2%; R19.7 million), Allograft Bone Grafts (2%; R18.4 million), Intraocular Lenses (2%; R15.7 million), and Synthetic Vascular Grafts (2%; R13.2 million), highlighting the importance of orthopaedic, trauma, reconstructive, ophthalmic, cardiovascular, and ENT procedures within the healthcare system.

The supplier landscape is moderately concentrated, with Stryker South Africa (14%; R111.5 million), Smith & Nephew (12%; R94.2 million), Safarmex (9%; R74.4 million), and Johnson & Johnson Medical (9%; R74.2 million) accounting for approximately 44% of total category expenditure, while the top ten suppliers contribute around 70% of total spend.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Stryker South Africa	R111.5	14%
Smith & Nephew	R94.2	12%
Safarmex	R74.4	9%
Johnson & Johnson Medical	R74.2	9%
Ortho-Xact	R42.2	5%
Vertice Healthcare	R40.4	5%
B. Braun Medical	R36.5	5%
Professional Orthopaedics	R33.9	4%
Medhold Medical	R22.5	3%
Zimmer Biomet South Africa	R20.6	3%

The dominance of global implant manufacturers such as Stryker, Smith & Nephew, Johnson & Johnson, Zimmer Biomet, B. Braun, and specialised orthopaedic suppliers indicates that South Africa remains highly dependent on imported implant

technologies, particularly for orthopaedic reconstruction, trauma fixation, cardiovascular interventions, and advanced surgical implants.

Surgical instruments, trays and bowls

The Surgical Instruments, Trays and Bowls category generated total expenditure of R427.6 million over the review period, increasing from R39.1 million in 2022/23 to R128.8 million in 2025/26, with expenditure peaking at R133.2 million in 2023/24. The category achieved a strong CAGR of 49%. The largest expenditure categories are Delivery Instrument Sets (11%; R47.1 million), Surgical Staplers (11%; R46.7 million), and Surgical Drills (11%; R45.2 million), which together account for approximately one-third of total category spend. Other key expenditure areas include Forceps (8%; R34.0 million), Dressing Trays (6%; R25.7 million), Circumcision Devices (3%; R12.2 million), Cutters (3%; R10.9 million), Medical Saws (2%; R9.3 million), Haemoclip Cartridges (2%; R8.9 million), and Diathermy Plates (2%; R8.7 million).

The supplier landscape is moderately concentrated, with Grobir Medical Suppliers (11%; R46.4 million), B. Braun Medical (9%; R39.8 million), Medtronic Africa (7%; R30.5 million), and Stryker South Africa (6%; R27.2 million) accounting for approximately 33% of total expenditure. Additional key suppliers include Medhold Medical (5%), Lolo & Lolo Development Services (5%), Logan Medical & Surgical (4%), Vertice Healthcare (3%), Karl Storz Endoscopy South Africa (3%), and Johnson & Johnson Medical (3%). The supplier mix is notable because it includes several globally recognised surgical technology manufacturers and specialist distributors, particularly in areas such as surgical stapling, endoscopy, orthopaedic instrumentation, powered surgical tools, vessel-sealing technologies, and minimally invasive surgery solutions.

Supplier	Total procurement value 2022/23 to 2025/26 (In R Mn)	Share
Grobir Medical Suppliers	R46.4	11%
B. Braun Medical	R39.8	9%
Medtronic Africa	R30.5	7%
Stryker South Africa	R27.2	6%
Medhold Medical	R20.7	5%
Lolo & Lolo Development Services	R19.9	5%
Logan Medical & Surgical	R16.0	4%
Vertice Healthcare	R14.1	3%
Karl Storz Endoscopy (South Africa)	R13.0	3%
Johnson & Johnson Medical	R12.2	3%

The Surgical Instruments, Trays and Bowls category exhibits a high degree of import dependency, with the RT252-2025 tender showing a very high percentage of contracted supply originating in Pakistan and no South African-manufactured instrument present anywhere in the contract. Supply is concentrated within the Sialkot manufacturing cluster and reaches the public sector through local distributors including Premier Endoscopy, Unicore Holdings, Tara Healthcare, Access Medical, Tecmed, National Medical Supplies and Aloe Medical Supplies, which function as import channels rather than local manufacturers. This dependence intensifies in high-value surgical technologies such as staplers, drills, saws, haemoclip systems and diathermy products, where procurement is concentrated among Medtronic, Johnson & Johnson, Stryker, B. Braun and Karl Storz, and where proprietary consumables and servicing requirements raise switching costs. Domestic value capture is presently confined to instrument repair, servicing and calibration. Import substitution is unlikely to be achievable in the medium term, as hand-held instrument manufacture requires surgical-grade steel forging, hardening and hand-finishing capability that does not exist locally at commercial scale, and the more realistic opportunity lies in refurbishment, sharpening and sterile reprocessing, which would capture value across the instrument lifecycle rather than at the point of purchase.

Reference List

Africa Health Business. (2026). *Health as an investment: Powering impact, sustainability and economic growth in Africa: Africa Health Business Symposium 2026 full plenary session report.* https://africahb.com/wp-content/uploads/2026/06/20260617_AHBS-2026-Full-Plenary-Session-Report.pdf

Competition Commission South Africa. (2019, September). *Health market inquiry: Final findings and recommendations report.* <https://www.compcom.co.za/wp-content/uploads/2020/01/Final-Findings-and-recommendations-report-Health-Market-Inquiry.pdf>

Council for Medical Schemes. (2025). *Healthcare utilisation annexures 2024.* <https://www.medicalschemes.co.za/publications/#2009-3817-wpfd-industry-report-2024-1764849328>

Department of Trade, Industry and Competition. (2024). *Medical technology masterplan (2024-2035).* https://www.thedtic.gov.za/wp-content/uploads/2024_Med-Tech-Master-Plan.pdf

Department of Trade, Industry and Competition. (2026). *South Africa's industrial development strategy 2026.* https://www.thedtic.gov.za/wp-content/uploads/South-Africas-Industrial-Development-Strategy_2026.pdf

Goemans, B., McLaughlin, R., Bailey, A., Casarin, A., Hunt, B., & Krige, N. (2018). *Medical devices: An innovation guide from lab to commercialisation: Route-to-market guide for inventors.* University of Cape Town, Research Contracts & Innovation (RC&I). https://www.sarima.co.za/wp-content/uploads/2019/01/r2m_guide_01.pdf

Impact Global Health, & PATH. (2026, July). *The diagnostics deficit: Funding, access, and preparedness gaps in African health systems.* https://media.path.org/documents/APP_IGH-PATH_policy_brief_2_.pdf

Medical Device Manufacturers of South Africa. (2021, January). *MDMSA industry booklet.* <https://assets.ctfassets.net/z7v5mgmkh5m2/1ofSmG6dGaX9icdYVc8jMs/3a72b16f4a0b0016c8f76843b1c7f171/13-MDMSA-Booklet-Jan21-corrected.pdf>

Mofo, L., Chigumira, G., & Nyakabawo, W. (2024). *Draft of the South African medical devices masterplan: Value chain 2024.* Trade & Industrial Policy Strategies. https://www.tips.org.za/research-archive/trade-and-industry/item/download/2619_676699da48a5601ce9f8f3bbedf08fd4

Narsai, K., Baldassarri, E., Pedersen, J., & Petersen, C. (2022, October). *Phase 1 report: Medical devices market study report.* HealthValue Consulting (Pty) Ltd for the Localisation Support Fund. <https://www.lsf-sa.co.za/reports/market-access-for-local-accredited-manufacturers-of-medical-devices-in-south-africa-by-the-lsf>

Narsai, K., Baldassarri, E., Pedersen, J., & Petersen, C. (2023, February). *Phase 2 report: Medical devices market study report.* HealthValue Consulting (Pty) Ltd for the Localisation Support Fund. <https://www.lsf-sa.co.za/reports/market-access-for-local-accredited-manufacturers-of-medical-devices-in-south-africa-by-the-lsf>

National Health Laboratory Service. (2022). *Annual report 2021/22.* https://www.nhls.ac.za/wp-content/uploads/2022/10/NHLS_AR_2022_web_version.pdf

National Health Laboratory Service. (2023). *Annual report 2022/23.* https://www.nhls.ac.za/wp-content/uploads/2023/11/241023-NHLS-Annual_Report.pdf

National Health Laboratory Service. (2024). *Annual report 2023/24*. https://www.nhls.ac.za/wp-content/uploads/2025/03/NHLS_Annual_Report_2023-2024.pdf

National Health Laboratory Service. (2025). *Annual report 2024/25*. https://www.nhls.ac.za/wp-content/uploads/2025/10/NHLS_Annual_Report_2024-2025.pdf

Parliamentary Monitoring Group. (2026, August 5). *Colloquium on South Africa's industrial development strategy 2026 Day 2 (with Deputy Minister)*. https://pmg.org.za/committee-meeting/43448/?utm_campaign=minute-alert&utm_medium=email&utm_source=transactional

Portfolio Committee on Trade, Industry and Competition. (2026). *MedTech industry presentation*. https://pmg.org.za/committee-meeting/43448/?utm_campaign=minute-alert&utm_medium=email&utm_source=transactional

South African Health Products Regulatory Authority. (2025, February 27). *Guideline for classification of medical devices and IVDs* (Version 5, SAHPGL-MD-04). https://www.sahpra.org.za/wp-content/uploads/2025/03/SAHPGL-MD-04_v5-Guideline-for-Classification-of-MD-and-IVDs.pdf

South African Health Products Regulatory Authority. (2026). *Medical devices registration feasibility study report*. https://www.sahpra.org.za/wp-content/uploads/2025/03/SAHPGL-MD-04_v5-Guideline-for-Classification-of-MD-and-IVDs.pdf

South African Medical Research Council. (2022). *The medical devices landscape in South Africa*. <https://www.investsa.gov.za/wp-content/uploads/2022/04/SAMRCMedicalDeviceLandscapeReport2022-003.pdf>

Workshop on Advancing Local MedTech Manufacturing and Innovation in South Africa. (2026, March 16). *Key insights from the workshop on advancing local MedTech manufacturing and innovation in South Africa* [Workshop summary report].



PROUDLY SUPPORTING LOCAL INDUSTRY

