FACT FILE

SAMED &

THE SOUTH AFRICAN MEDTECH INDUSTRY

SAMED
advancing patient care through MedTech

Content

South African Medical Technology Industry Fact File

SAMED

About SA**MED**

Who we are

The South African Medical Technology Industry Association (SAMED) is a not-for-gain industry association founded in 1985. The objective of the Association then was to engage with the Regulatory Authorities and call for the registration of medical devices.

Over the years SAMED's membership has grown and includes multinationals, distributors, wholesalers and local manufacturers of medical devices, medical equipment, and in vitro diagnostics (IVDs) (collectively referred to as 'medical technology').

SAMED is the voice of the South African medtech industry. The Association encompasses the full spectrum of diverse players involved in the supply of medtech products and services to diagnose, monitor, treat and rehabilitate patients. SAMED is committed to enabling a sustainable, ethical, and transformed medical technology industry that ensures patient access to medical technologies.

In line with our Constitution, we provide the medtech industry with a collective, objective, and credible platform to engage with all stakeholders. Our vision is to partner with our stakeholders to drive the medtech industry to new frontiers and contribute towards enabling a sustainable healthcare system. Medical technology plays a vital role across the continuum of patient care and the medtech sector plays a significant role in providing effective and efficient health care for all South Africans.

About SA**MED**

What we do

On behalf of our members, SAMED engages and collaborates with policymakers, regulators, healthcare organisations, professional societies, funders and international agencies and alliances.

We research, assemble, and share knowledge and experiences to empower our members to jointly and sustainably advance the medtech industry.

We stand for good governance and support patient-centric policies that enable people to live healthy and productive lives.

We provide solutions that enhance our country's healthcare system, and its productivity and accountability.

We host regular forums and training workshops on matters that impact the business and sustainability of our members.

We educate members and stakeholders and implement tools to facilitate ethical marketing and business practices across the medtech value chain and the entire health system. We also partner with key stakeholders to combat corruption within medtech and healthcare.

We collect and provide members with data that aids them in making informed business decisions. We subscribe to the Government Gazette, Parliamentary Monitoring Group, and tender bulletins. SAMED is also a member of the business collective, Business Unity South Africa (BUSA).

We advocate for harmonised standards and regulatory requirements for the manufacture, supply, and use of medtech and are members of international organisations, the GHWP and the GMTA.

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About SA**MED**

Our strategic objectives

The SAMED board sets and regularly reviews our strategic objectives in consultation with SAMED committees and members. Our strategy is informed by our values:

TRUST

Trust is at the heart of successful relationships. It is the glue that binds industry parties, so they spend less time protecting themselves and more time on collaboration. Trust is the natural result of a myriad thoughts, intentions, words and actions.

INTEGRITY

Integrity is acting with honour regardless of whether actions are public – and honouring your commitments. It's about nurturing an ethical culture that permeates the entire organisational ecosystem. Having integrity leads to smarter, more sustainable decisions and practices.

INCLUSIVITY

Inclusivity and diversity go hand-in-hand to allow for meaningful opportunities for all stakeholders to contribute to our industry. Inclusivity entails involvement of diverse companies and distinct people to share their abilities and experiences. Inclusivity boosts efforts with greater innovation, skills and creativity.

UNITY

SAMED is the voice of the medtech industry. We use a united voice to address common matters. Our industry has a far greater reach and impact when our representatives, individual members companies and their individual employees speak with the same united voice.

RESPECT

Respect is about showing humility and being sensitive. Being treated respectfully promotes a collaborative culture which motivates engagement, support, and performance, making it easier to achieve common goals. Respect requires introspection - thinking about how our word or actions affect our environment and the reputation of others. A lack of respect undermines the value all parties bring to the table and can erode the health and success of the relationship.

TRANSPARENCY

Being transparent is a core strength that speaks to one's authenticity and confidence. Sharing ideas and information allows industries to get new and often deeper perspectives, opinions, and ideas. Problems are solved faster and more efficiently if one is open and honest. Transparency builds trust, fosters shared accountability and raises ethical standards.

STEWARDSHIP

Stewardship refers to the responsibility to understand and manage the impact SAMED has on our members and their operational environment. Our role is to uphold the best interests of our members and the broader medtech sector. We are custodians of our members concerns, guardians of their sustainability and curators of their growth.

About SA**MED**

Our strategic purpose is underpinned by the need for sustainable economic and social transformation – to encourage a more diverse, equitable and inclusive medtech sector. The current SAMED strategic pillars are as follows:

Strive to safeguard, promote, and represent the common interests of members with all relevant authorities and stakeholders.

Our members and their common interests inform all other facets of the SAMED strategic objectives. Our objectives align with our members' operational environment and considers the diverse portfolio of companies and medtech products that we represent.

Drive compliance to ethical principles and practices in the conduct of member's businesses and affairs.

SAMED advocates for the self-regulation of the industry through the Medical Technology Code on Ethical Marketing and Business Practices (the Code). The implementation of the Code is supported by an independently managed toll-free whistleblowing hotline (0800 00 04 68).

The Code assists medtech companies and healthcare providers in ethical marketing and business practices and interacts with third-party anti-corruption initiatives, including the Health Sector Anti-Corruption Forum which SAMED joined in November 2019.

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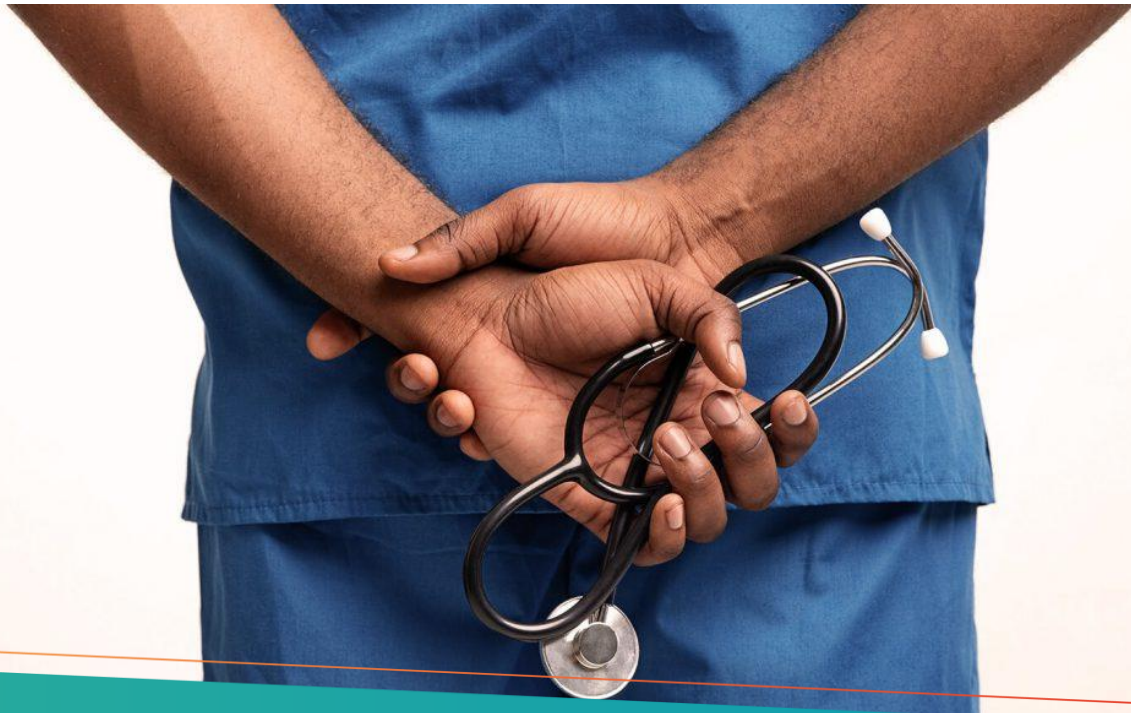
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About SA**MED**

Shape best practice in standards, policies, and regulatory requirements applicable to the medtech industry.

To benefit health outcomes and national socio-economic progress, South Africa needs a well-resourced and capacitated regulatory system for the manufacture, supply and procurement of medical technology. To strengthen the overall regulatory framework, we continually engage with Government i.e. the South African Health Products Regulatory Authority (SAHPRA), the Department of Health, Department of Trade, Industry and Competition, Department of Science and Innovation, Department of Small Business Development and National Treasury, the public and private health sector procurement and supply chain managers, healthcare providers and funders.

Promote access to medtech for better patient outcomes.

SAMED is a patient-centric partner. Medtech not only save lives but improve outcomes and quality of life for many patients.

We promote access to medtech that is appropriate and relevant to South African patients and support a value-based agenda that measures and builds health services based on both patient outcomes and the cost of care (it's not just one or the other).

SAMED promotes clear, transparent, practical procurement processes that recognise the complexities of the medtech industry, ensure continuity of supply, and contributes to healthcare system efficiency, accountability, and sustainability.

SAMED supports a procurement model that appreciates the value of innovative solutions and enhances competition by various players in the industry to advance diversity across the medtech supply chain. Innovation translates into value when it prevents disease and decreases patient waiting times, length of hospital stays, morbidity, and mortality.

A value-based healthcare and procurement approach:

- Helps healthcare providers and health systems plan for the short/medium/long-term implications of buying medical technology.
- Positions decisions on procurement within the context of wider patient and societal outcomes together with the life-cycle cost of healthcare delivery and services.

Support medtech growth for healthcare sustainability.

We believe that South Africa's home-grown manufacture of medical technology should be actively promoted and stepped up. A strong local medtech manufacturing sector is good for the economy and reduces dependence on imported medical technologies, which are subject to global availability. By manufacturing and buying locally, we can grow and keep expertise and skills within South Africa.

A more competitive local manufacturing capacity (coupled with the African Continental Free Trade Agreement) can enhance our trade and collaborations within the African Union and strengthen local and African health systems to bring the continent closer to universal health coverage. SAMED is a proud supporter and participant of the South African Medtech Master Plan.

We participate in the National Health Insurance and other policy discussions. SAMED supports universal health coverage and aims to ensure that it considers the value and innovation cycles of medtech.

SAMED regards transformation as an economic and social imperative. We are committed to transformation and believe we can drive meaningful and sustainable change by co-creating an eco-system that gives our members the tools and opportunities to transform their companies.

We have partnered with the Youth Employment Service to combat the rise in youth unemployment in South Africa and to contribute to sustainable skills growth and capacitation for our industry. This partnership has created 2063 youth jobs which translate into R 116 353 200 injected into local economies through youth Salaries.

About SA**MED**

Our committees

The SAMED board establishes and guides the work of committees that operationalise the SAMED strategy and listen to, represent, and support our members. We encourage voluntary membership of committees by SAMED members. Committees' operations are supported by the SAMED Secretariat.

Our Code Committee promotes the Code and whistleblowing hotline as the cornerstones of the medtech industry's self-regulation. The Code Committee is currently undertaking efforts to have the Code recognised by the Minister of Health in line with current legislature as to make it applicable and enforceable to the entire medical technology sector.

Our Market Access Committee improves collaboration with public and private healthcare facilities and funders, strengthens supply chain management and tender processes, strengthens reimbursement and HTA mechanisms in the private and public sectors and participates in Council for Medical Schemes consultations.

Our National Health Insurance (NHI) Committee reviews, supports and contributes to the shaping of policy, legislation, and the practical implementation of the NHI.

Our Regulatory Committee contributes to a harmonised medical technology legislative environment, engages on policy matters with the South African Health Products Regulatory Authority (SAHPRA) and other agencies tasked with the quality, safety and effectiveness of medical technology and hosts regulatory forums to assist members with the implementation of regulations.
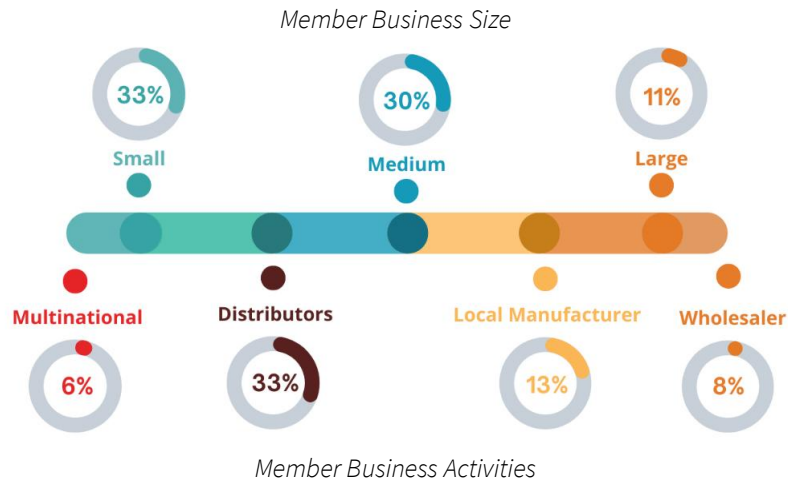
Our Diversity in Medtech Committee champions the transformation of the medical technology industry and individual companies as a socio-economic imperative and key factor of the industry's sustainability. The committee promotes the objectives of diversity, equity, and inclusion among members. Two key initiatives are our partnership with the YES programme and the Medtech Women Empowerment Index.

Our members

SAMED membership comprises ordinary and associate members. A breakdown of our member companies' business size and activities can be seen below.

Member Business Size

33%	30%	11%
Small	Medium	Large

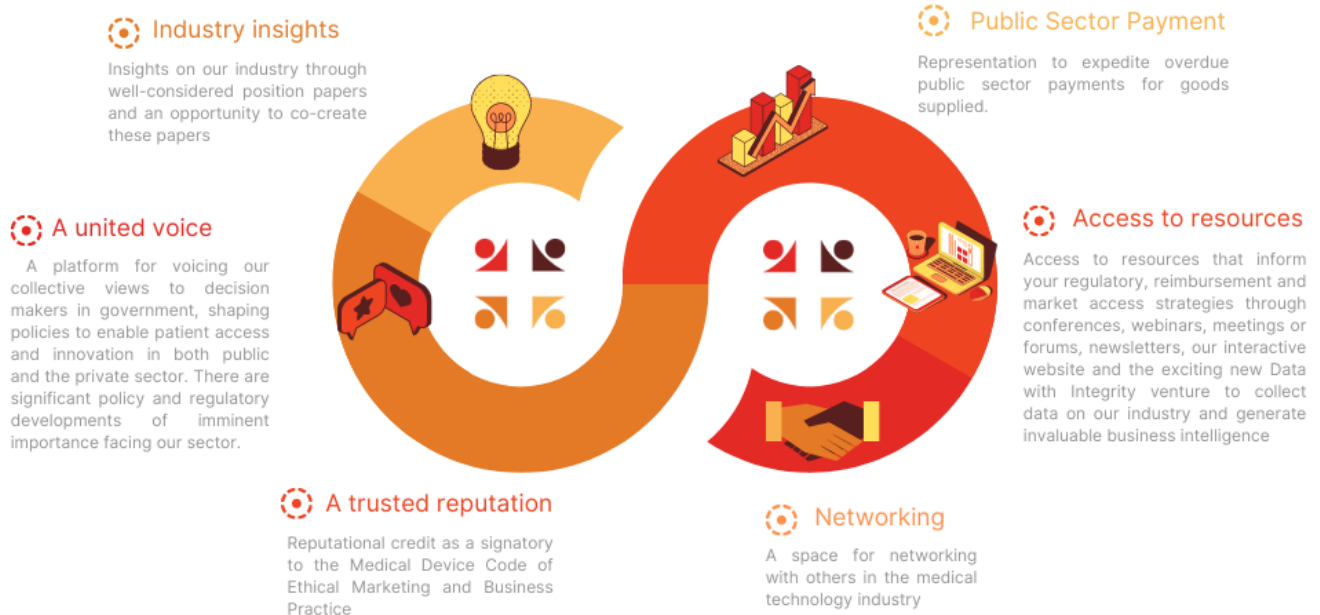| Multinational	Distributors	Local Manufacturer	Wholesaler
6%	33%	13%	8%

Member Business Activities

Please see the SAMED website (www.samed.org.za) for a list of our members.

The average member company age is 17 years, however, 7% are start-ups and several companies were established more than 50 years ago. The membership we represent employs as many as 10 000 people and encompasses more than 500 000 different medical technologies used in the diagnosis, prevention, treatment and amelioration of disease and disability. These range from sticking plasters and wheelchairs through to pacemakers and replacement joints.

Associate members include consultants, training providers, conformity assessment bodies and logistic companies operating in the medical technology industry.

We offer the following benefits to our members:

Industry insights
Insights on our industry through well-considered position papers and an opportunity to co-create these papers

Public Sector Payment
Representation to expedite overdue public sector payments for goods supplied.

A united voice
A platform for voicing our collective views to decision makers in government, shaping policies to enable patient access and innovation in both public and the private sector. There are significant policy and regulatory developments of imminent importance facing our sector.

Access to resources
Access to resources that inform your regulatory, reimbursement and market access strategies through conferences, webinars, meetings or forums, newsletters, our interactive website and the exciting new Data with Integrity venture to collect data on our industry and generate invaluable business intelligence

A trusted reputation
Reputational credit as a signatory to the Medical Device Code of Ethical Marketing and Business Practice

Networking
A space for networking with others in the medical technology industry

The South African
medtech market

Medical technology is an essential element of health provision, along with care by healthcare practitioners, healthcare organisations and pharmaceuticals. The medtech industry in South Africa is diverse – it spans from local manufacturers that specialise in a limited portfolio of products to multinational and distributors that cover numerous products and healthcare categories.

Size and composition of the market

South Africa is one of the largest markets in the Middle East and Africa (MEA) region. Its large population (63.02m mid 2024, Stats SA) and Africa's most industrialised economy support this emerging market.

The medtech market is poised for considerable growth . In 2021, the South African medtech market was estimated to be worth R21 billion projected to grow to R29.6 billion by 2025 .

The **South African medical devices market** is projected to be worth **approximately USD 1.12 billion in 2025**, with a **CAGR of around 6.9%** through 2032, reaching about **USD 1.67 billion by 2032**

Fewer than 5% of local industry players locally manufacture devices, with 90% of the market supplied by imports .

South Africa is the primary business hub for the medical technology industry in sub-Saharan Africa. A major

Top Sub-Saharan destinations for export of medtech from SA, 2017	
Country	**USD Millions**
Namibia	**31.46**
Botswana	**18.85**
Uganda	**9.80**
Swaziland	**9.69**
Zimbabwe	**9.55**
Zambia	**5.90**
Kenya	**5.85**
Mozambique	**4.82**
Lesotho	**3.91**
Malawi	**3.47**
Tanzania	**3.29**
Mauritius	**2.64**
Democratic Republic of Congo	**2.23**

Fitch Solutions; https://www.export.gov/article?id=South-Africa-medical-devices; Africa Health: Market Insights: South Africa Medical Devices Market 2019
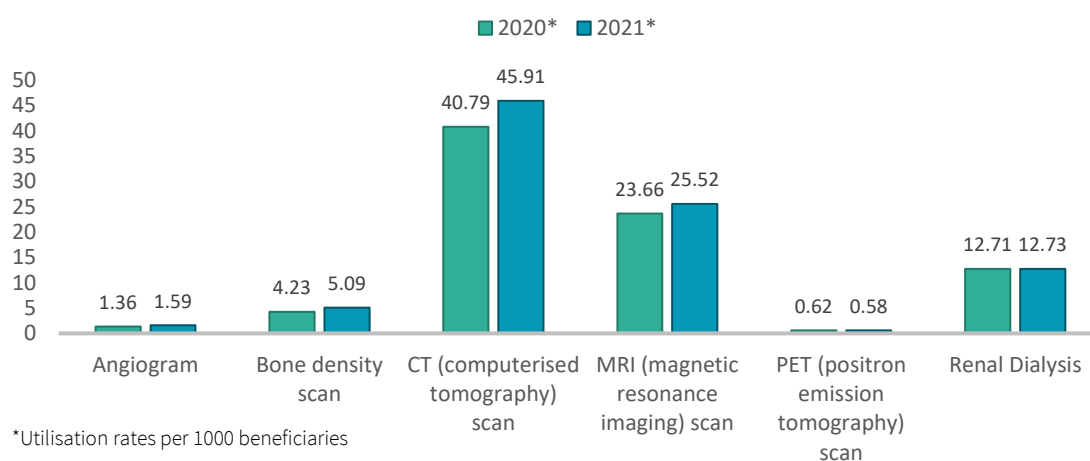
The South African
medtech market

More than 80% of the industry are privately-owned small and medium-sized enterprises (SMMEs), with less than 50 employees.

South Africa has numerous incentives available to medical device innovators and manufacturers that span the value chain from early development to industrialisation and growth. All of these are offered by publicly funded departments and agencies.

South Africa's spending on medical technology and devices as a proportion of wealth is on par with other MEA region markets. The use of medical technologies in South Africa can be gauged by looking at the utilisation of certain medtech by medical scheme beneficiaries. By the end of 2021 medical schemes had 8.95 million beneficiaries, or about 15% of the South African population. Table below sets out the utilisation of several procedures using medtech. Most of these would have been performed in the private sector and are an underestimate of the total number of procedures performed in the country.

PROCEDURES

■ 2020* ■ 2021*

	Angiogram	Bone density scan	CT (computerised tomography) scan	MRI (magnetic resonance imaging) scan	PET (positron emission tomography) scan	Renal Dialysis
2020*	1.36	4.23	40.79	23.66	0.62	12.71
2021*	1.59	5.09	45.91	25.52	0.58	12.73

*Utilisation rates per 1000 beneficiaries

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The South African
medtech market

Medical technology regulations, procurement, and reimbursement

Due to the nature of the medical technology sector, various registration, licence, and quality management regulations apply to the industry.

Legislative frameworks and agencies relevant to health regulation include the following:

National Health Act which provides a framework for a structured uniform health system, considering the obligations imposed by the Constitution and other laws on the national, provincial, and local governments regarding health services.

Regulations for Medical Devices and IVDs, issued under the Medicines and Related Substances Act 1965.

The South African Health Products Regulatory Authority (SAHPRA), including the department of radiation control, has the mandate to ensure that the products under its charge are safe, effective, of good quality and in the interest of the public throughout their lifecycle. See www.sahpra.org for the current legislation, regulations and guidelines pertaining to medical devices and in-vitro diagnostics.

Current requirements include a Medical Device Establishment Licence with a product listing by risk classification. Renewal of Establishment Licences after a period of 5 years must be accompanied by a valid ISO13485 certificate.
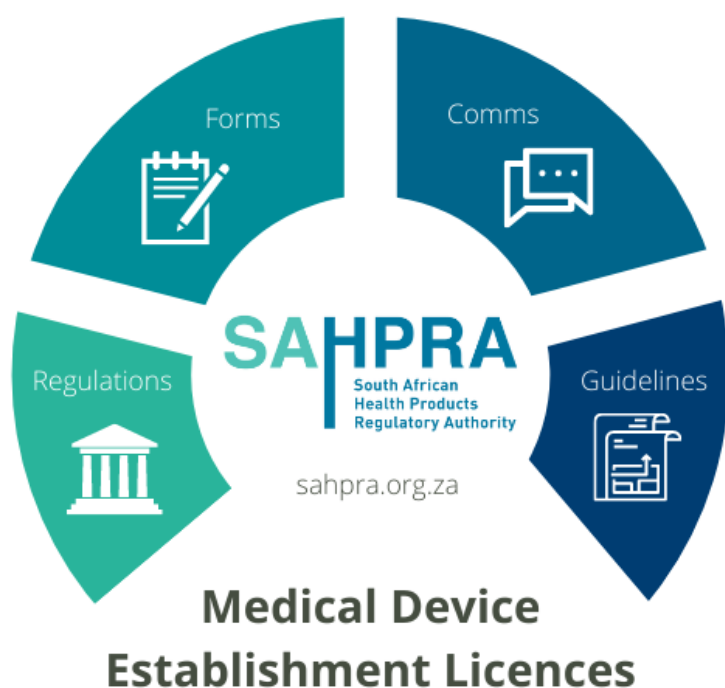
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Licences Issued

A single organisation can hold several licences as it may have a manufacturing, distributing and wholesale licence for several sites across the country.

Types of Licences

42% of licences are distributor, 32% are manufacturer and 25% are wholesale licences.

Establishment Location

61% of licences are for establishments in Gauteng, 17% are in the Western Cape, and 14% are in KwaZulu-Natal

The next step in applying the regulation of medical devices in South Africa will be product registration. This process is still in development but will involve a Registration Call-Up Plan.

The South African medtech market

The Council for Medical Schemes (CMS) is a statutory body established by the Medical Schemes Act (131 of 1998) to provide regulatory supervision of private health financing through medical schemes.

Firms operating in South Africa must consider Broad-Based Black Economic Empowerment (B-BBEE) while conducting business. The Black Economic Empowerment (BEE) Act, No. 53 of 2003 empowers the Minister of Trade, Industry and Competition (the dtic) to issue Codes of Good Practice and publish Transformation Charters; establish the BEE Advisory Council; and make provision for other related matters.

Protection of Personal Information Act (POPIA) became effective on 1 July 2020. Its purpose is to protect people by protecting their personal data. The Act impacts on doctors, healthcare professionals, medical aids, insurance companies, pathologists, administrators, hospitals, and organisations that need to protect employee and patient personal health data.

The National Health Insurance programme is in the early stages of implementation.

The Public Procurement Act No. 28 of 2024 governs all government procurement within South Africa and aims to reform public procurement processes.

The Act establishes a single framework for procurement by all organs of state, promoting fairness, transparency, and cost-effectiveness while combating corruption. It seeks to make public procurement more transparent and competitive and introduce measures to ensure the integrity of the procurement process. It is anticipated that this will make tendering, procurement, and payment across the public sector more predictable and accountable. The Act is not yet in effect; the President will bring its provisions into operation through a proclamation in the Government Gazette, possibly in a phased approach

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South African
health facilities

South Africa currently has a two-tiered healthcare system, comprising the larger public (approximately 80% of the population) and the growing private sector. The country spent 9.11% of its GDP on healthcare in 2019 – higher than the 5% the World Health Organization (WHO) recommends for a country of its socio-economic status. However, despite this high expenditure, health outcomes remain poor in comparison with similar middle-income countries. This is primarily attributed to the inequities between the public and private sectors .

Government is the major purchaser of healthcare equipment and supplies in South Africa, associated with a public healthcare sector comprising 7 901 facilities . While a form of national tendering exists, each province has its own tendering system.

## Primary healthcare in focus

The National Department of Health views a transition from a curative model of health service to one that promotes primary healthcare delivered as close to the community as possible as one of the key strategies to strengthen the health system and improve health outcomes.

Different initiatives, fostered by the NHI programme, are directed towards achieving this, and improving access to and quality of primary and family healthcare. They include projects to strengthen existing and open new clinics and introduce and capacitate community health workers. In some areas, there is growing collaboration between the public and private health providers.

Hospital sector

South Africa has roughly 400 public hospitals and 200 private hospitals within its nine provinces . Public sector hospitals are split into three categories: academic (or tertiary), district and regional hospitals. Most hospitals in South Africa, both public and private, are general hospitals. However, there are specialist hospitals and medical centres dedicated to areas such as psychiatry, cardiology, gynaecology, and orthopaedics . Private hospitals mostly form part of hospital groups operating in South Africa. Private hospital groups contribute R55.5 billion to the national economy, equivalent to 11.3% of GDP .
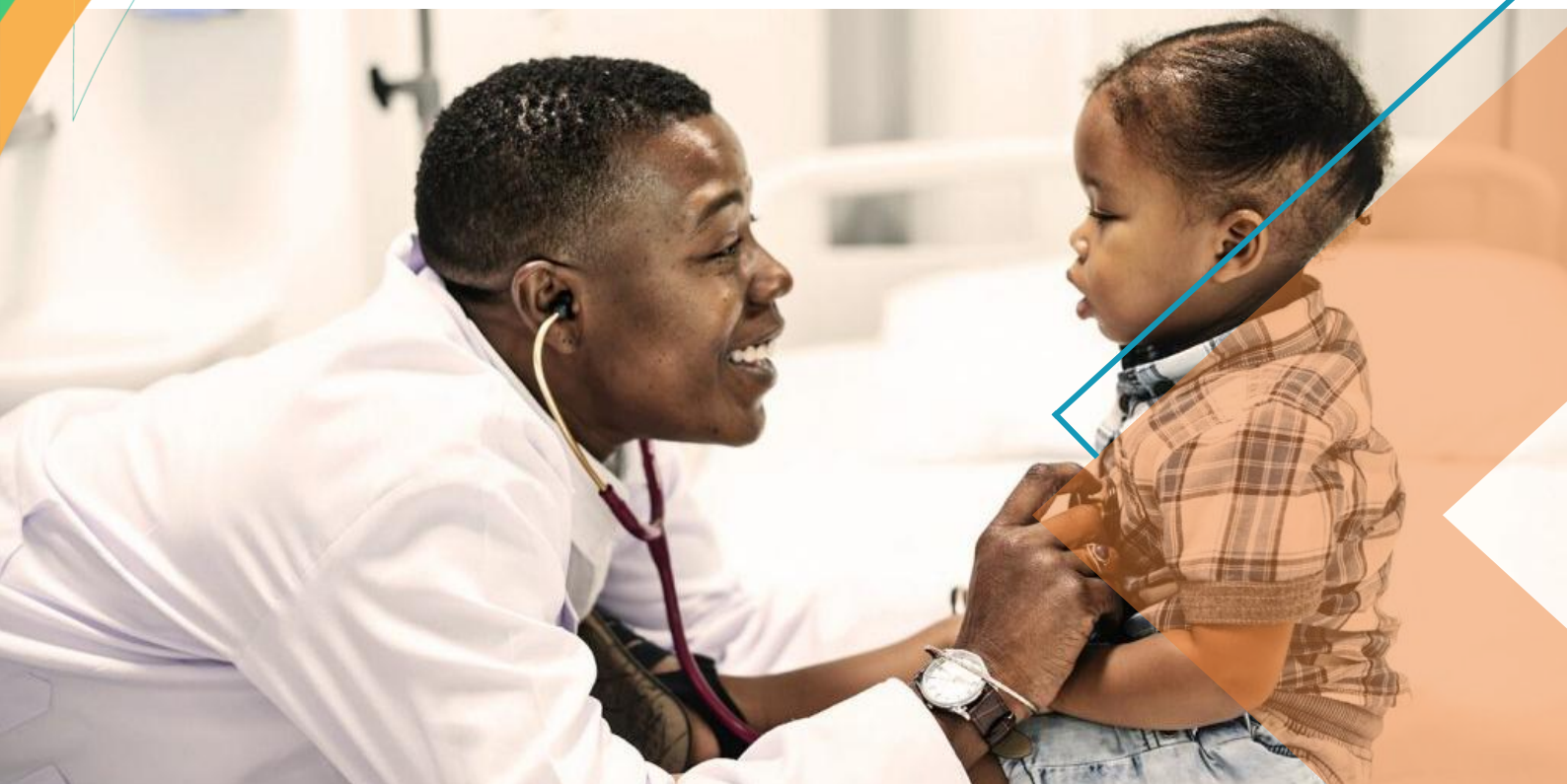
For more on the public sector, see links below.

- National Department of Health: http://www.health.gov.za/
- Eastern Cape Department of Health: http://www.ecprov.gov.za/Pages/default.aspx
- Free State Department of Health: http://www.fshealth.gov.za/portal/page/portal/fshp/intranet
- Gauteng Department of Health: https://www.gauteng.gov.za/Departments/DepartmentDetails/CPM-001006
- KwaZulu Natal Department of Health: http://www.kznhealth.gov.za/
- Limpopo Department of Health: http://www.doh.limpopo.gov.za/
- Mpumalanga Department of Health: http://www.mpuhealth.gov.za/
- North West Department of Health: http://health.nwpg.gov.za/dohnw/
- Northern Cape Department of Health: http://www.northern-cape.gov.za/
- Western Cape Department of Health: https://www.westerncape.gov.za/dept/health

Information on some of the largest private sector groups is available below:

- Life Healthcare Hospitals: www.lifehealthcare.co.za
- Mediclinic: www.mediclinic.co.za
- National Hospital Network (NHN): www.nhn.co.za
- Netcare Ltd: www.netcare.co.za
- Joint Medical Holdings: https://jmh.co.za/
- Lenmed: https://www.lenmed.co.za/about-lenmed/
- Day Hospital Association of South Africa: https://www.dhasa.co.za/
- Hospital Association of South Africa: https://hasa.co.za/

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