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Review Article

A Comparative Overview of Medical Device Registration in BRICS Countries

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ABSTRACT

An overview of the medical device registration processes across BRICS countries (Brazil, Russia, India, China and South Africa). Its purpose is to give a comprehensive analysis of regulatory frameworks, approval procedures and market entry requirements that vary from region to region. In these diverse regions each country presents different challenges and opportunities for medical device manufacturers due to various levels of regulatory rigor, bureaucratic processes and market dynamics at play. For instance, Brazil and Russia have complicated regulatory pathways that require substantial documentation plus take long to approve. On the other hand, India as well as China have fast track procedures which are moving towards international standards but pose problems concerning localization and conformity issues. As regards regulation South Africa offers a simpler environment; however, it possesses obstacles like small size of the domestic market or unique local needs. Moreover, this summary highlights significant comparisons between countries with regard to use of national regulating bodies, systems used in product classification, surveillance after sale of goods among other things. It is important that the stakeholders comprehend these subtleties if they intend to operate properly within BRICS markets while observing their individual rules.

INTRODUCTION

The abbreviation for the grouping of five significant emerging economies is BRICS. Brazil, Russia, India, China and South Africa. Though all five of the BRICS members are G-20 members, they are all developing or newly industrialized nations that stand out for having sizable, rapidly expanding economies and a big impact on regional and international issues. The developing markets of Brazil, Russia, India, China, and South Africa are together referred to as BRICS, and they are all thought to be at a comparable stage of newly advanced economic development. "The BRICS" or "the BRICS economies" are the usual ways to refer to it.

Definition of BRICS countries

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1) Brazil: A major economy in Latin America, known for its diverse culture and significant natural resources.
2) Russia: The largest country in the world by land area, rich in energy resources and with a strong influence in global geopolitics.
3) India: One of the most populous countries with a rapidly growing economy and a significant role in the global technology and service sectors.
4) China: The world's most populous country and a leading global economic power with a major influence in international trade and finance.
5) South Africa: The most developed country in Africa, with a significant impact on the continent's economic and political landscape.

Table 1: BRICS healthcare market for medical devices

Size	Brazil	Russia	India	China	South Africa
Market size	~$4.8 billion	~$3.7 billion	~$6.7 billion	~$78 billion	~$1.7 billion
Growth rate	~5.2% annually	~4.2% annually	~11% annually	~13% annually	~7.5% annually

Methodology

The registration process of the medical device in BRICS countries such as Brazil, Russia, India, China, and South Africa. The information is collected from regulatory authorities, legislations, guidelines and experts' opinions.

Table 2: list of BRICS countries regulatory authority & their function

Sr no.	Name of countries	Regulatory authority	Function
1	Brazil	Brazilian Health Regulatory Agency (ANVISA)	ensure the population's health is protected by implementing hygienic controls over the manufacturing, distribution, and use of goods and services that are governed by health regulations. This includes oversight of associated settings, procedures, materials, and technology, as well as port, airport, and border controls.
2	Russia	Ministry of Health of the Russian Federation	supervises and gives approval for the marketing and distribution of pharmaceuticals for both human and veterinary use.
3	India	Central drug standard control organization (CDSCO)	The CDSCO headquarters is responsible for regulatory oversight of drug imports, approval of new medications and clinical trials, meetings of the medications Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), and approval of specific licenses as the Central License Approving Authority.
4	China	National Medical Products Administration (NMPA)	keeping an eye on and guaranteeing the security of four main product families: food, medications, medical supplies, and cosmetics.
5	South Africa	South African Health Products Regulatory Authority (SAHPRA)	regulating (monitoring, evaluating, investigating, inspecting; and registering) all health products.

MEDICAL DEVICE REGISTRATION IN BRICS COUNTRIES

A. BRAZIL:

Table 3: About the Brazil country:

Area	8,514,215 km ²
Population	217.0 million
Capital city	Brasília (population 2.82 million)
Language	Portuguese
Currency	Brazilian real (BRL)
Government	the Federative Republic of Brazil

Medical device regulation in Brazil:

Latin America's largest market for medical devices is Brazil, which has a well-established yet intricate regulatory framework. In Brazil, the National Health Surveillance Agency (ANVISA) oversees the regulation of medical equipment. Emergo's Brazilian team, which has offices in São Paulo and Brasília, has the know-how to assist you in navigating ANVISA's regulatory requirements so you may start selling your product in Brazil. The Brazilian Good Manufacturing Practice (B-GMP) regulations must be followed by all manufacturers. If your equipment is of a higher class, you need to get certified by ANVISA for B-GMP compliance and go through an audit. Get the technical dossier and application forms ready to submit to ANVISA.

Medical device definition in Brazil

Anything that the manufacturer intends to use, alone or in combination, in humans for any of the following specific medical purposes and whose primary intended action is not accomplished by pharmacological, immunological, or metabolic means in the human body, but which may be assisted in its intended action by such means: Any instrument, apparatus, equipment, implant, in vitro diagnostic medical device, software, material, or other article The following are examples of healthcare practices: a) disease diagnosis, prevention, monitoring, and treatment; b) injury or impairment diagnosis, monitoring, treatment, or repair; c) anatomical, physiological, or pathological process or state investigation, replacement, or alteration; d) support or maintenance of life; e) control or support of conception.

Table 4: Medical device classification system in Brazil

International classification	Risk level	Example
Class I	Low risk	Bandages, elastic bandages, and simple crutches.
Class II	Medium risk	Dental drills, surgical instruments, and imaging devices for diagnosis.
Class III	High risk	Implanted defibrillators, pacemakers, and prosthetic heart valves.
Class IV	Maximum risk	Radiation therapy and extracorporeal circulation system.

Table 5: Medical device regulatory approval procedure in Brazil

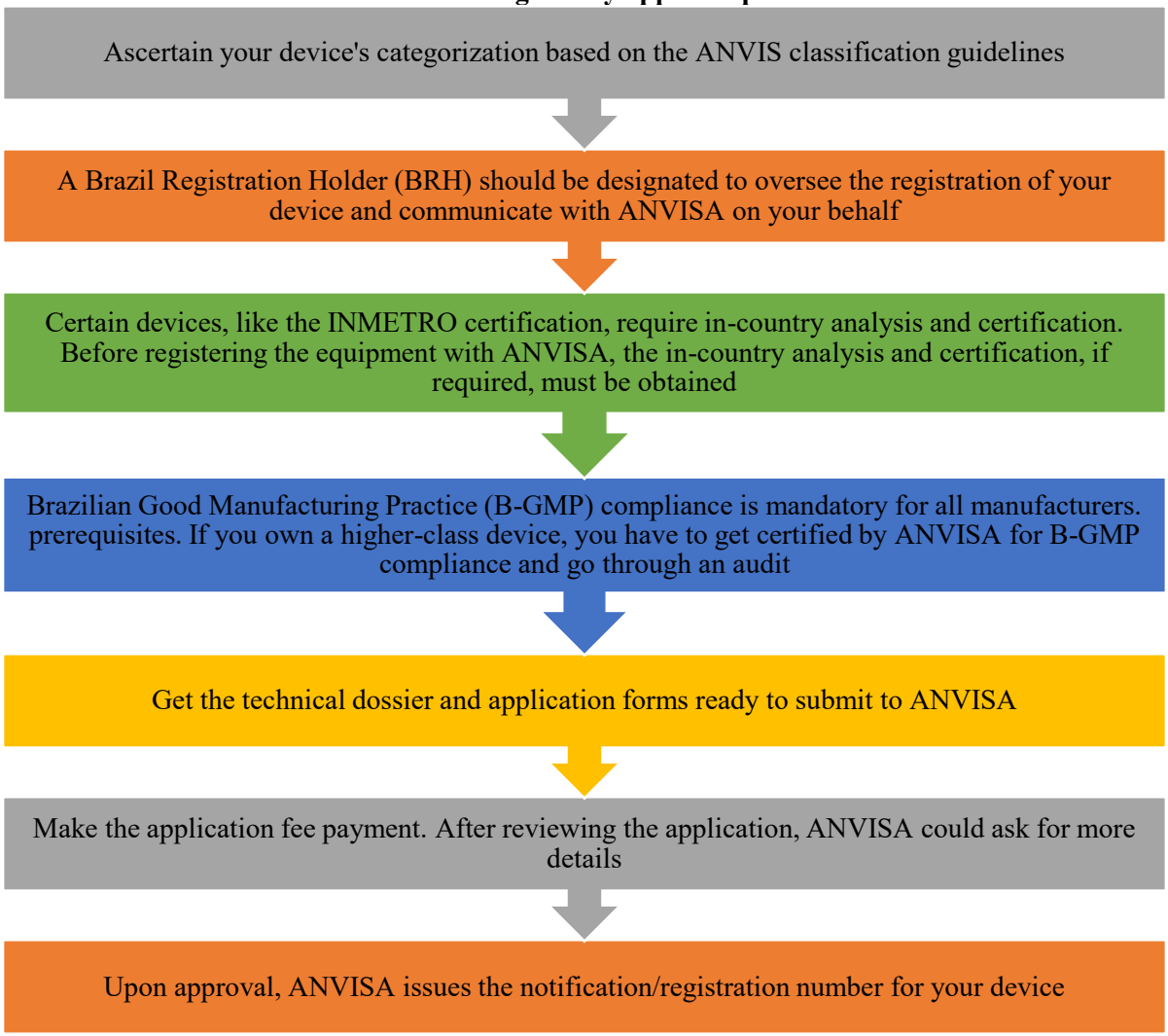

Table 6: Additional information of medical device in Brazil

<table>
<tr><td>Approval timeline</td><td>MD Class I & II: 30 days; MD Class III & IV: 250 days. GMP Certification: 365 days. GMP by MDSAP: 180 days. If more data or testing is needed, the approval procedure may take longer.</td></tr>
<tr><td>License validity period</td><td>Class I & II: - Does not expire.
Class III & IV: - 5 years</td></tr>
<tr><td>Fees</td><td>Notification/Registration
<table>
<tr><th>Device</th><th>Small company (BRL)</th><th>Large company (BRL)</th></tr>
<tr><td>Class I and II</td><td>$351</td><td>$3,514</td></tr>
<tr><td>Class III and IV</td><td>$2,127</td><td>$21,274</td></tr>
</table>
Authorization of Operation (AFE)
<table>
<tr><th>Type</th><th>Small Company [BRL]</th><th>Big Company [BRL]</th></tr>
<tr><td>Manufacturer</td><td>$1,952</td><td>$19,524</td></tr>
<tr><td>Distributor</td><td>$1,418</td><td>$14,183</td></tr>
<tr><td>Importer</td><td>$1,418</td><td>$14,183</td></tr>
</table></td></tr>
</table>

	Good Manufacturing Practices (GMP)		
	Type	Small Company [BRL]	Big Company [BRL]
	MERCOSUL	$2,659	$26,593
	Foreign	$72,804	$72,804

B. RUSSIA:

Table 7: About the Russia country

Area	17.1 million km²
Population	144.2 million
Capital city	Moscow
Language	Russian
Currency	Russian Ruble
Government	The federal executive body of state power of the Russian Federation

Russia medical device regulatory authorities

Roszdravnadzor is the name of the regulatory organization in Russia in charge of medical devices. It reports to the Russian Federation's Ministry of Health. Furthermore, Roszdravnadzor is subservient to three scientific expert institutes, often known as Federal State institutes, or FGBUs. The responsibility of this agency's Medical Device Registration and Control Department is medical device registration.

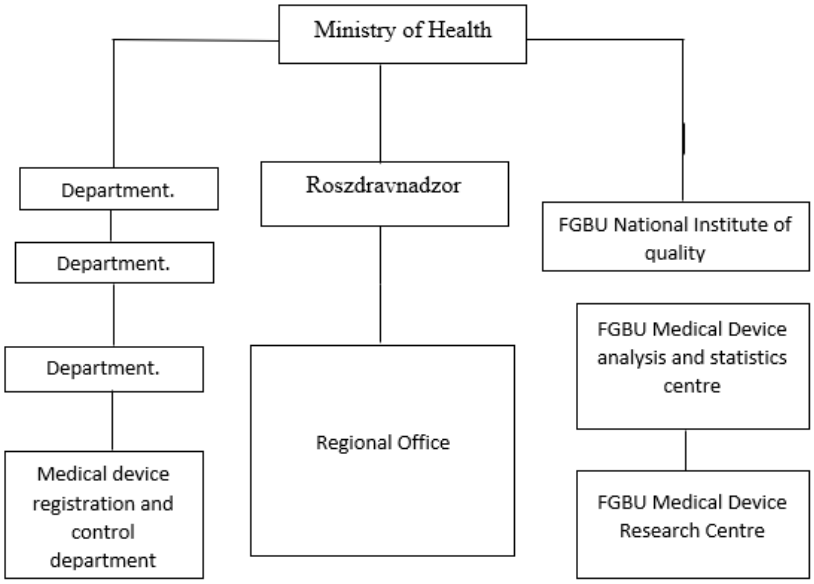

Figure 1: Russia medical device regulatory authorities

Medical device registration and control decisions in Russia are made by the Medical Device Registration and Control Department. Additionally, it is in charge of approvals for modifications and revisions as well as registration suspension and cancellation. The Registration Certificate is what a medical device manufacturer gets in the event that their registration is accepted.

Medical device definition in Russia

According to Article 38, a "medical device" is any tool, apparatus, appliance, material, or other item, including software, that is intended for use for therapeutic and diagnostic purposes (i.e., disease, injury, or handicap diagnosis, prevention, monitoring, treatment, alleviation, or compensation), and that does not accomplish its primary intended action in or on the human body

through pharmacological, immunological, or metabolic means.

Table 8: Medical device classification system in Russia

Risk	Class
Low	Class 1
Moderate	Class 2a
High	Class 2b
Critical	Class 3

Table 9: Medical device registration procedure in Russia

For Class II, Class IIb, and Class III: As per the clinical data standards set forth by RZN, carry out extra testing or trials in Russia. The registration is put in "suspended" status for this period. Send RZN your clinical results and a request to continue the registration process.

For every kind of device: The dossier undergoes Stage 2 evaluation. If approved, RZN lists the product in the registration database on its website and issues a Registration Certificate. Registrations are perpetual.

For every class of device: Select a Russian Declarant and submit an application for certification as a Declaration of Conformity (DoC). A combined quality and product safety certificate are called a DoC certification. Test reports, ISO 13485 certificate, registration certificate, and other documentation can be required.

For all device classes: Your device has to display the DoC symbol once the DoC certificate has been granted. It is now approved for you to sell your gadget in Russia. The manufacturer may choose to extend the validity of the DoC certificate for up to three years

Table 10: Additional information of medical device in Russia

Timeframe	New Registration: 10–16 months (including time to reply to RZN's comments and request that RZN evaluate more documents)		
Fees (New application)		Class 1	USD 750
		Class 2a	USD 1020
		Class 2b	USD 1310
		Class 3	USD 1730
Fees (Manufacturer)	No manufacturer registration fee is required.		
License Validity	Licenses issued in Russia do not expire.		
License Transfer	The license transfer requires a modification to the AR and is applicable in Russia.		

C. INDIA:

Table 11: About the India country

Area	3.287 million km²
Population	1.45 billion
Capital city	New Delhi

Language	Hindi and English
Currency	Indian Rupee (INR)
Government	"union" or "central" government

Medical device definition in India

A device to be used internally or externally to diagnose, cure, mitigate, or prevent diseases or disorders in humans or animals.

Table 12: Medical device classification system in India

International classification	Risk level	Examples
Class A	Low risk	Elastic bandages, Hot water bags, Sphygmomanometer.
Class B	Low moderate risk	Blood glucose monitoring devices, Nebulizers, Wheelchairs.
Class C	Moderate high risk	X-Ray machines, Infusion pumps, MRI machines.
Class D	High risk	Heart valves, Implanted pacemakers, Artificial joints.

Table 13: Medical device Approval procedure in India

<table>
<tr><th>Classification</th><th>Approval Procedure</th></tr>
<tr><td>Class A</td><td rowspan="4">It is required of the applicant to designate an Indian Authorized Agent as their authorized representative. To receive approval, every medical device needs to be registered with CDSCO. The application can be submitted in paper form or electronically using the SUGAM site. It must be submitted with the appropriate fees and other necessary documentation.
To manufacture, sell, or distribute Class A or Class B medical devices, an application for a license or loan license must be made to the State Licensing Authority.
<table>
<tr><td>Type</td><td>Application form</td><td>License form</td></tr>
<tr><td>License</td><td>MD-3</td><td>MD-5</td></tr>
<tr><td>Loan License</td><td>MD-4</td><td>MD-6</td></tr>
</table>
</td></tr>
<tr><td>Class B</td></tr>
<tr><td>Class C</td></tr>
<tr><td>Class D</td></tr>
<tr><td></td><td>To manufacture, sell, or distribute Class C or Class D medical equipment, an application for a license or loan license must be made to the Central Licensing Authority.
<table>
<tr><td>Type</td><td>Application form</td><td>License form</td></tr>
<tr><td>License</td><td>MD-7</td><td>MD-9</td></tr>
<tr><td>Loan License</td><td>MD-8</td><td>MD-10</td></tr>
</table>
</td></tr>
</table>

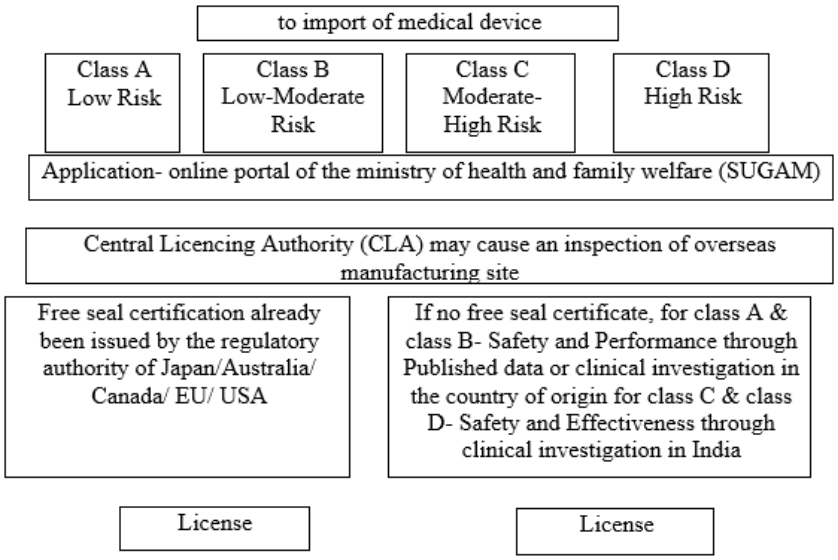

Figure 3: To manufacture medical device for Sale and Distribution

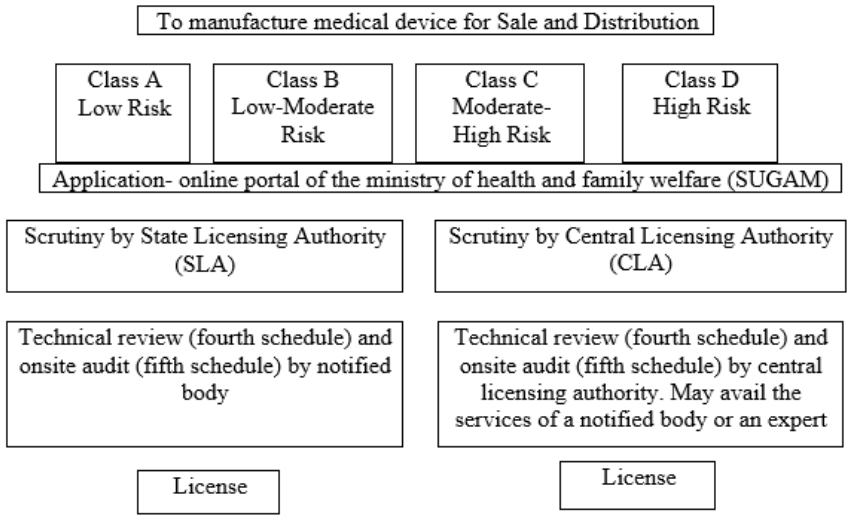

Table 14: Additional information of medical device in India

Approval timeline	Class A: License Grant by SLA: 45 days Audit of the production facility from the license issuance date for a period of 120 days Class B: A 90-day audit of the production site starting on the application date Inspection report delivered within 30 days to SLA License Grant by SLA: 20 days Class C and Class D: 45 days from the application date to complete the scrutiny audit of the production facility from the application date forward for 60 days.45 days from the date of the audit report is the license grant date.
License validity period	Does not end if the license retention fee (which is due every five years) is paid.
Fees	Class A or Class B: One Site - 5000 INR Each Distinct Medical Device - 500 INR Class C or Class D: One Site - 50000 INR Each Distinct Medical Device - 1000 INR

D. CHINA:

Table 14: About the China country

Area	9.597 million km²
Population	1.43 billion
Capital city	Beijing
Language	Mandarin, also call "Putonghua"
Currency	Chinese yuan (CNY) and renminbi (RMB)
Government	system of people's congress within the parameters of a unitary communist state

Medical Device Definition in China

In China, any instrument, apparatus, appliance, substance, or other item, whether used singly or in combination, is considered a medical device, as is the software required for its appropriate use.

Table 15: Medical device classification system in China

International Classification	Risk Level	Examples
Class I	Low risk	Bandages, examination gloves, and surgical gowns.
Class II	Medium risk	Diagnostic reagents, powered wheelchairs, and artificial joints
Class III	High Risk	Implantable pacemakers, artificial heart valves, and certain diagnostic imaging equipment.

Table 16: Medical Device Approval Procedure in China

Class I medical devices must be examined, certified, and given a registration certificate by the municipalities' government's drug regulatory body, which is composed of districts.

Class II medical devices must be examined, approved, and registered by municipalities, autonomous areas, and provinces that are directly under the control of the federal government's drug regulatory agencies.

The drug regulatory body directly under the State Council is responsible for inspecting, approving, and granting registration certificates for Class III medical devices.

Table 17: Additional information of medical device in China

Approval timeline	1 month to 18 months (Depends on Class of medical device)
License validity period	5 years
Fees	Class II: - $30623 Class III: - $44839

Table 18: Medical Device Classification Fee Structure in China

Class	NMPA Review Fee	Review Timeframe
Low Risk Class I	NA	4 weeks
Medium Risk Class II	210,900 RMB (~$30,000 USD)	12-24 months
High Risk Class III	308,800 RMB ($44,000 USD)	12-24 onths

E. SOUTH AFRICA:

Table 19: About the South Africa country

Area	1.22 million km²
Population	63 million
Capital city	Cape Town, Pretoria, Bloemfontein
Language	Zulu and Xhosa
Currency	The South African rand
Government	Constitutional republic, parliamentary republic

Medical Device Definition in South Africa

Any tool, appliance, substance, machine, apparatus, implant, or diagnostic reagent used or purportedly suitable for use, manufactured or sold for use in the mitigation, modification, monitoring, or prevention of disease, abnormal physical or mental states, or the symptoms thereof, is considered a medical device in South Africa. Restoring, adjusting, or changing any physical, mental, or biological function. **OR**

The diagnosis or prevention of pregnancy; or designated as a medical device by the Minister by notice in the Gazette, which includes any part or accessory of a medical device; and which does not achieve its purpose through chemical, pharmacological, immunological, or metabolic means in or on the human body but may be assisted in its function by such means.

Table 20: Medical device classification system in South Africa

International Classification	Risk Level	Examples
Class A	Low risk	Bandages and basic wound dressings.
Class B	Low–moderate risk	Powered wheelchairs and electrotherapy devices.
Class C	Moderate – high risk	Diagnostic X-ray equipment and implantable hearing aids.
Class D	High risk	Implantable heart pacemakers and insulin pumps.

Table 21: Medical Device Approval Procedure in South Africa

Medical equipment classified as class A are exempt from registration requirements, with the exception of those that require sterilisation or have a measuring function

The authority should receive an electronic application together with the necessary paperwork, which includes a list of medical devices categorized by Global Medical Device Nomenclature Code (GMDN), QMS details, a free sale certificate, and a certificate of compliance or analysis. Authority will grant clearance after assessing the documents' completeness

In South Africa, the applicant needs to designate an Authorized Representative. the licensing application for the production, import, or export of IVDs, or medical devices. As decided by Council, the applicant must submit certified proof of certification to a quality management system

To meet a quality standard set by the Council, a certified copy of the conformity assessment certificate—issued by a Conformity Assessment Body is required. The medical device will be added to the Medical Device Register upon approval

Table 22: Additional information of medical device in South Africa

Approval timeline	6-8 weeks
License validity period	5 years
Fees	R25 200

	BRAZIL	RUSSIA	INDIA	CHINA	SOUTH AFRICA
Flag					
Regulatory Authority	Brazilian Health Regulatory Agency (ANVISA)	Ministry of Health of the Russian Federation	Central drug standard control organization (CDSCO)	National Medical Products Administration (NMPA)	South African Health Products Regulatory Authority (SAHPRA)
Medical device Regulatory Law	Regulation for Medical Devices in Brazil is RDC 751/2022	the Decree of the Government of the Russian Federation No. 1416 of 27/12/2012	Medical devices are regulated as Drugs under the Drugs and Cosmetics Act 1940 and Rules made thereunder in 1945	Medical Device Registration Certificate from the National Medical Product Administration (NMPA).	The South African Health Products Regulatory Authority oversees medical devices in accordance with the Medicines and Related Substances

					Act of 2015, Act No. 1417.
Language	Portuguese	Russian	English	Chinese	English
Pre-market Approval	Manufacturers must submit a detailed dossier that includes clinical data, technical documentation, and evidence of compliance with standards.	Manufacturers must provide detailed technical documentation, including safety and efficacy data.	Manufacturers need to submit an application including clinical data, technical documentation, and evidence of compliance with Indian standards.	Detailed documentation is required, including clinical trials data and compliance with Chinese standards.	A comprehensive submission is required, including technical documentation and evidence of safety and efficacy.
Classification	I, II, III, IV	I, IIa, IIb, III	A, B, C, D	I, II, III	A, B, C, D
Clinical Trials	Not always required, but ANVISA may request them based on the device's classification.	Required for certain high-risk devices, and trials must be conducted in Russia.	Required for certain high-risk devices, and trials must be conducted according to Indian regulations.	Required for many devices, often involving trials conducted within China.	Required for certain devices, and trials must comply with South African regulations.
Quality System	Medical Devices, or IVDs, cannot be marketed unless Brazilian Good Manufacturing Practices, or BGMPs, are followed. Regulation RDC 665/2022 establishes the requirements for the Quality Management System (QMS) for medical devices in Brazil. Along with the US, Canada, Australia, and Japan, Brazil is a participant in the MDSAP Program (Medical Device Single Audit Program).	ISO 13485:2016 and ISO 9001	ISO 13485:2016	ISO 13485:2016	ISO 13485:2016
Applicant	Authorized Local Representative (BRH).	Local Authorized Representative.	The foreign producer is required to designate an Indian Authorized Representative/Agent as their local authorised representative. This person will be in responsibility of both product importation and post-market surveillance inside the designated territory.	Legal Agent.	Manufacturers of medical devices that have submitted an application for an establishment license are required to choose an Authorized Local Representative who will be based in South Africa and be in charge of adhering to local laws, rules, and regulations.

Timeframe and Fees	Notification path: the notification number will be issued within 30 days. The "Registro" registration procedure takes 8 to 15 months. Taxes are required for both types of registration.	Timeframe: 6-16 months.	The price of the Device Master File varies based on the product's risk class. The price of an item is $50 for a Class A device, $1,000 for a Class B device, and $1,500 for a Class C or D device. The price varies based on the risk class even with the Plant Master File. For example, a Class A device costs $1,000, a Class B device costs $2,000, and a Class C or D device costs $3,000. Moreover, registration times differ based on the type of device.	Class I devices (alert): 5 to 6 months. Class II and Class III devices (registration): from 15 to 32 months. Currently, Class II and Class III Medical Device registration requires government costs ranging from 210.900,00 RBM to 308.800,00 RMB.	After the initial $1,010 charge is paid, the establishment license will be issued in around 6 to 8 weeks. The cost of renewal is $282 each year.
Validity	The class I and class II notification are valid indefinitely. The Registro registration is valid for 5 years.	Class I medical devices may last up to 8 months, and Class III devices may last up to 16 months.	Import licences are valid for five years.	Notification validity: unlimited. Registration certificate validity: 5 years.	Licence: 5 years
Labelling and documentation language	The documentation and the labelling must be provided in Portuguese.	Documentation and labelling must be provided in Russian.	You can draft the product registration paperwork in English. Medical devices intended for professional use may have labels and usage instructions available in English, while devices intended for home use may have Indian labels and instructions. In every instance, the Indian Authorized Representative's identity details must be included together with the foreign manufacturers.	Labelling and documentation have to be done in Chinese.	Labelling and documentation have to be done in English.
Market Entry Requirement	Requires a local representative or distributor. Approval can take several months to over a year, depending on device complexity and risk classification.	A local representative or authorized distributor is mandatory. The process involves a state registration certificate and	Requires an import license and a local agent or distributor. Fast-track procedures are available but still require compliance with local standards and regulations.	Requires registration with NMPA and often a local agent. China's market is rapidly evolving, and manufacturers	An application in the format required by law. Labels, IFUs, Package Inserts or promotional materials. Letter designating the individual as the

	Post-market surveillance and compliance with Brazilian standards are essential.	may require local testing. Regulatory changes and evolving standards can add to the complexity.	Local conformity and adaptation to Indian standards are crucial.	must stay updated with regulatory changes and localization requirements. There are also fast-track pathways for certain types of devices.	original manufacturer's authorized representative.
Useful information	Devices with the same intended function and/or made of comparable materials can be combined under a single registration. Active medical devices that adhere to IEC 60601-1 need to bear the INMETRO mark and be certified by a laboratory approved by INMETRO. For certain electromedical devices and inactive gadgets, the INMETRO Certification is a pre-market prerequisite that is good for five years.	Usually, samples are required for on-site testing.	The CDSCO requires device clearance from a reference country, such as the US, Canada, Europe, the UK, Switzerland, Australia, or Japan, but not from the home country of the foreign producer. Central Drugs Standard Control Organization (CDSCO) is the regulatory authority. Two authorities have been set up to issue certificates: State Licencing Authority (Class A and B devices) and Central Licencing Authority (Class C and D devices) Classification of Medical Devices: class A (low risk), class B (low-moderate risk), class C (moderate-high risk), class D (high risk)	The Legal Agent name shall be included in the Registration Certificate, together with the manufacturer's one.	The South African Health Products Regulatory Authority (SAHPRA) is now wrapping up the product registration procedure. It will be specified in the next "Registration Call-Up Plan" and will depend on the kind and class of device.

CONCLUSION

The medical device registration process varies significantly across BRICS nations, presenting both challenges and opportunities for manufacturers. While countries like India and China offer expedited pathways, they also demand localization and conformity. In contrast, Brazil and Russia have stringent regulations and lengthy approval times. South Africa, though simpler, has a smaller market and specific local needs. To succeed in these markets, stakeholders must thoroughly understand the unique regulatory landscape of each country and adapt their strategies accordingly. In order to guarantee the security and effectiveness of healthcare goods, the BRICS nations—Brazil, Russia, India, China, and South Africa—must go through a difficult but necessary registration procedure for medical devices. Every nation has its own set of regulations, with differing demands for local representation, documentation, and clinical trials. In spite of these distinctions, the BRICS countries

are increasingly moving toward harmonization and closer cooperation in an effort to improve market access and expedite the registration process. To receive approval, producers typically have to navigate a complex web of standards and procedures that frequently call for thorough submissions and adherence to regional laws.

As these nations' regulatory frameworks develop further, conforming to international norms and encouraging increased collaboration can make it easier for medical devices to enter the market, which will eventually advance innovation and access to healthcare around the world.

Brazil:

To register medical devices under ANVISA, comprehensive documentation and local trials are needed. Manufacturers are required to collaborate with a regional agent.

Russia:

Roszdravnadzor is in charge of registration, providing thorough documentation and perhaps conducting extra testing. The direction of recent reforms is toward global alignment.

India:

To register a device, CDSCO needs a risk-based classification system, comprehensive product information, and local representation.

China:

Comprehensive clinical data and adherence to regional norms are required by NMPA, while there is a tendency to streamline the procedure.

South Africa:

SAHPRA mandates comprehensive clinical and technical records that are increasingly in line with global norms. Agents in the area are required for registration.

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