IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

COMPARISON OF INDIA AND MALAYSIA MEDICAL DEVICE REGISTRATION PROCESS

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Abstract: Indeed, the Medical Device industry has experienced significant growth and innovation over the last two decades. Medical Devices are essential tools used in healthcare settings for the diagnosis, treatment, and monitoring of various medical conditions. They play a crucial role in improving patient outcomes, enhancing the quality of healthcare, and extending life expectancy. India had indeed published the Medical Device Rules in 2017, which aimed to revise the regulatory process for Medical Devices. The Central Drugs Standard Control Organization is indeed the primary regulatory body for medical devices and pharmaceuticals in India. It operates under the Ministry of Health and Family Welfare. The Medical Device Authority is indeed the regulatory body responsible for medical devices in Malaysia. The Medical Device Authority operates under the Ministry of Health Malaysia and plays a crucial role in ensuring the safety, efficacy, and quality of medical products available in the Indian as well as Malaysian market.

Keywords: Medical Device, CDSCO, MDA, Regulation, Registration

Introduction:

The increasing importance of medical devices in the healthcare sector and the necessity for robust regulatory frameworks to ensure their safety and efficacy. As medical technology continues to advance and new devices are introduced into the market, it becomes imperative for regulatory agencies to stay updated and adapt to these changes effectively. Companies operating in the medical device industry must be well-informed about the ever-changing regulatory requirements and standards to bring their products to market successfully. Failure to comply with these regulations can lead to delays in marketing approval, resulting in financial losses, missed market opportunities, and potential damage to the company's reputation.(1)

Medical Device:

A "medical device" refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article that is intended by the manufacturer to be used, alone or in combination, for human beings. The device is intended for one or more of the specific medical purposes listed below:

i. Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
ii. Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury.
iii. Investigation, replacement, modification, or support of the anatomy or of a physiological process.
iv. Supporting or sustaining life.
v. Control of conception.
vi. Disinfection of medical devices.

The term "medical device" encompasses a wide range of products, spanning from simple and basic items like Ice bags, Tongue depressor to highly sophisticated and advanced technologies such as Cardiac Pacemaker, Proton Therapy Devices. The regulatory definition of a medical device typically covers a broad spectrum of healthcare-related products, regardless of their complexity or technical sophistication. This includes items that serve various purposes and are intended to be used for human medical interventions or health-related purposes.(2) Table 1 explain the based classification of Medical Device.

table 1: classification of medical device

Classification	Risk Level	Example
Class A	Low risk	Surgical retractors, Thermometer
Class B	Low to Moderate risk	Hypodermic needle, Suction equipment
Class C	Moderate to High risk	Orthopedic implants, Bone fixation plate
Class D	High risk	Heart valves, Implantable defibrillator

Some more examples of medical devices:

1. Blood Glucose Meter
2. Nebulizer
3. Magnetic Resonance Imaging (MRI) Scanner
4. Pulse oximeter
5. Stent

India:

Regulatory Bodies:

The Central Drugs Standard Control Organization (CDSCO) is indeed India's main regulatory body for pharmaceuticals and medical devices. It operates under the purview of the Ministry of Health and Family Welfare (MOHFW) and is responsible for regulating the import, manufacture, distribution, and sale of medical devices and pharmaceuticals in India. The Drug Controller General of India (DCGI) holds a pivotal position within the CDSCO. The DCGI is the key official responsible for overseeing and regulating the approval and licensing of various medical products, including:

1. Approval of Manufacturing: The DCGI is responsible for approving the manufacturing of certain categories of drugs, including vaccines, large volume parenteral, blood products, and r-DNA derived products.
2. Specific Medical Devices: The DCGI is involved in regulating the approval process for specific medical devices that are deemed as drugs under the Indian regulatory framework. These medical devices fall under the purview of the Drugs & Cosmetic Act and Rules (DCA).
3. New Drugs: The DCGI is also responsible for granting marketing approvals to new drugs that are proposed to be introduced into the Indian market.

Regarding medical devices in India, the manufacturing, import, sale, and distribution of medical devices are regulated under India's Drugs & Cosmetic Act and Rules (DCA).(3)

Approval Process of Medical Device in India:

The process for marketing medical devices in India involves obtaining the necessary licenses and approvals from the Central Drugs Standard Control Organization (CDSCO).

1. Wholesale License: Companies intending to import or distribute medical devices in India must obtain a Wholesale License in Form 20B (for allopathic drugs) or Form 21B (for medical devices). This license allows the entity to engage in wholesale activities related to medical devices.
2. Import License: For importing medical devices into India, a company needs to obtain an Import License in Form 8 (for drugs) or Form 9 (for medical devices). The Import License permits the importation of medical devices into the country.
3. Registration for Notified Medical Devices: Certain medical devices and In-Vitro Diagnostic (IVD) devices are classified as Notified Medical Devices & IVDs and must be registered with the CDSCO before they can be marketed in India.
   The registration process involves submitting the required documentation, including technical data and safety information, to demonstrate compliance with applicable standards and regulations.(4) In Figure a, the registration procedure for medical devices in India is briefly described.

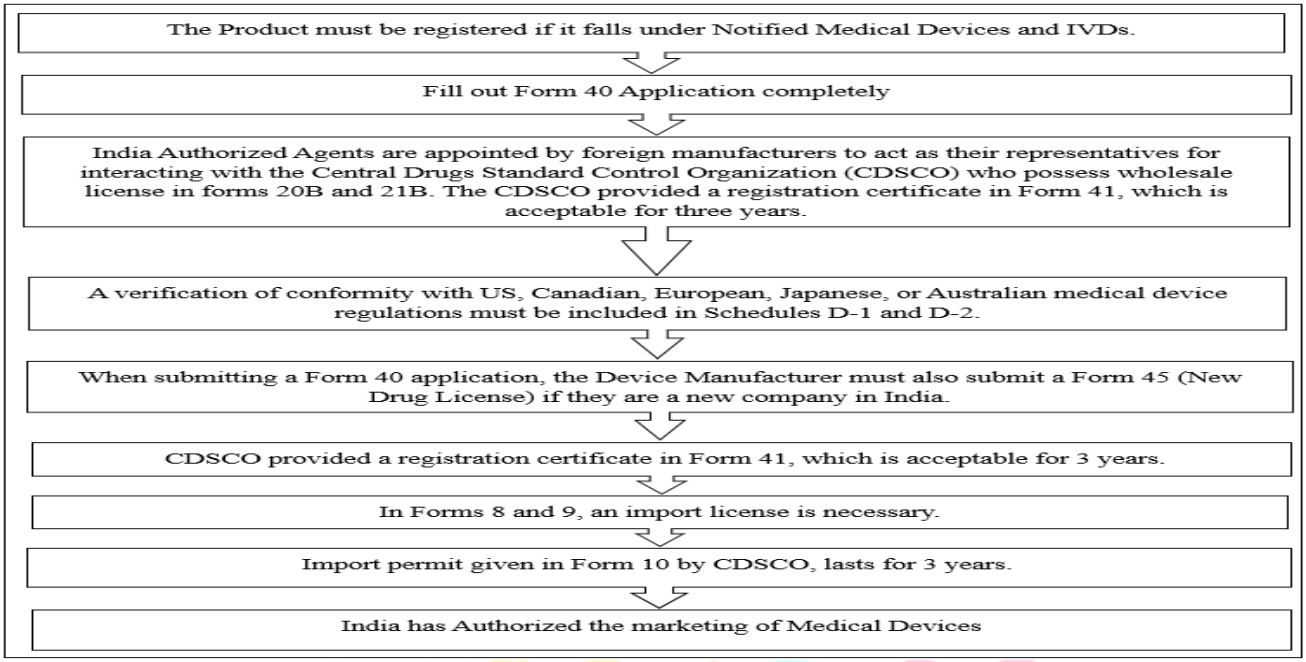

fig. a: approval process of medical device in India

Regulatory Guideline required for Registration of Notified Medical Device in India:

India had implemented certain regulations for the registration of notified medical devices under the Drugs and Cosmetics Act. Once the import license is secured, the manufacturer or Indian agent needs to apply for the registration of the notified medical device using Form 41. This form should be accompanied by specific documents as required under the applicable rules. The rules you mentioned, i.e., Rule 24-A, 25-B, 27-A, and 28-A of the Drug and Cosmetic Rules, may outline the necessary documentation to be submitted along with Form 41.

- Covering letter
- An authorization letters
- Filled Form 27
- Requesting Fee
- Power of Attomey
- Attested copy of wholesale license
- Attested and valid copy of free sale certificate
- Attested and valid copy of ISO 13485 Certificate
- Attested and valid copy of CE Full Quality Assurance certificate
- Duly notarized and valid copy of CE Design Certificate
- Duly notarized and valid copy of Declaration of Conformity
- Copy of latest Inspection/Audit Report carried out by Notified bodies
- Submit Pant/site master file
- Submit Schedule D(II)Device Master File (5)

Malaysia:

Regulatory Bodies:

The regulatory body responsible for medical devices in Malaysia is the Medical Device Authority (MDA), which operates under the Ministry of Health (MOH) Malaysia. The Medical Device Authority (MDA) was established to oversee the implementation of the Medical Device Act 2012 (Act 737) and the regulation of medical devices in Malaysia. The Act was introduced to regulate the import, export, manufacture, sale, and distribution of medical devices to ensure their safety, quality, and effectiveness.

The key functions of the Medical Device Authority (MDA) in Malaysia include:

1. Registration and Licensing: The MDA is responsible for registering and issuing licenses for medical devices that are intended to be imported, exported, manufactured, sold, or distributed in Malaysia.
2. Regulatory Oversight: The MDA ensures that medical devices comply with the relevant regulatory requirements and standards, aiming to safeguard public health and safety.
3. Post-Market Surveillance: The MDA conducts post-market surveillance activities to monitor medical devices' safety and performance once they are in use in the Malaysian market.
4. Market Authorization: The MDA assesses and approves applications for market authorization of medical devices based on their risk classification.
5. Establishment Inspection: The MDA conducts inspections of manufacturing facilities and establishments to ensure compliance with quality management systems and good manufacturing practices.(6)

Approval Process of Medical Device in Malaysia:

1. Medical Device Act 2012 (Act 737): The Medical Device Act 2012 is the legislation in Malaysia that governs the import, export, manufacture, sale, and distribution of medical devices. All medical devices intended to be placed on the Malaysian market after July 1, 2013, when Act 737 took effect, must be registered under this Act.
2. Medical Device Registration: Before a medical device can be imported, exported, or made available on the market in Malaysia, it must undergo registration with the Medical Device Authority (MDA), which operates under the Ministry of Health (MOH) Malaysia.
3. Medical Device Centralized Online Application System (MeDC@St): MeDC@St is an online, web-based system that serves as the platform for submitting medical device registration applications to the MDA. This centralized system facilitates the registration process and streamlines the application submission and evaluation.

Medical device manufacturers or their authorized representatives who intend to place medical devices in the Malaysian market must use the MeDC@St platform to apply for registration. The platform allows for efficient submission of required documentation, communication with the MDA, and tracking the status of the application. Figure b provide the steps to be taken before making an application for registration of Medical Device.(7) Table 2 provide the comparative difference between the India and Malaysia.

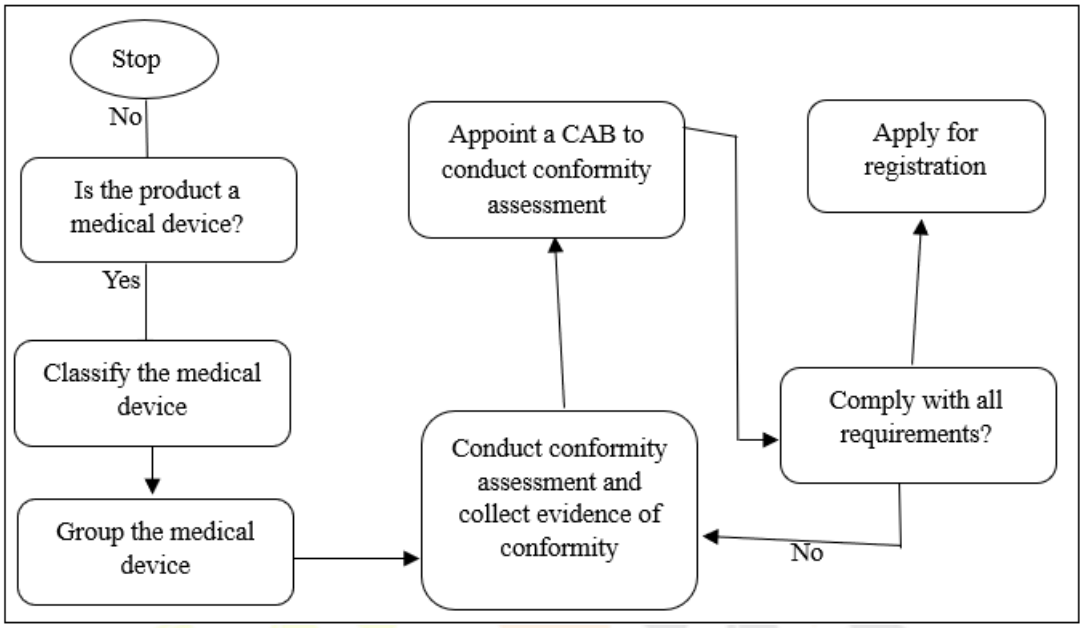

fig. b: steps and criteria for medical device registration

Medical Device Placement on the Malaysian Market:

a. Elements of conformity assessment
   - ✓ The elements of a conformity assessment system.

b. Conformity of the quality management system (QMS)
   - ✓ Quality management system (QMS)
   - ✓ System for post-market surveillance (PMS)

c. Conformity assessment of medical device safety and performance
   - ✓ Summary technical documentation i.e., Common Submission Dossier template (CSDT)
   - ✓ Declaration of conformity (DoC)

d. Registration
   - ✓ Registration of medical devices and establishments

e. Essential Elements of conformity assessment system:
   - ➢ Executive summary
   - ➢ Description of medical device
   - ➢ Summary of design verification and validation documents
   - ➢ Pre-clinical studies
   - ➢ Software validation studies
   - ➢ Clinical evidence
   - ➢ Medical device labeling
   - ➢ Manufacturer information
   - ➢ Special requirement for medical device used in clinical investigation

f. Conformity of the quality management system (QMS)

g. Conformity assessment of medical device safety and performance

h. Common Submission Dossier Template (CSDT)

The main sections of CSDT are;

1. Executive summary
   - • Introductory descriptive information
   - • Marketing history
   - • Intended use
   - • List of Regulatory approval
   - • Status of any pending application

- Safety and performance related information
- Relevant Essential Principles for Safety and Performance (EPSP) and method used to demonstrate conformity

2. Device description
   - Complete description of device
   - Principle of Operation
   - Risk class and Applicable rule
   - Description of accessories
   - Novel futures
   - Drawings and Diagrams
   - Intended use
   - Instruction for use
   - Contraindication
   - Warning
   - Precautions
   - Potential Adverse effect or side effects
3. Summary of design verification and validation documents
   - Reports of tests:
     i. Performance Testing o engineering tests;
     ii. laboratory tests;
     iii. biocompatibility tests;
     iv. animal tests;
     v. simulated use
4. Pre-clinical studies
5. Risk Analysis
6. Manufacture information (8)

table 2: comparison table for medical devices to India and Malaysia

S. No.	Point of Comparison	India		Malaysia	
1	Regulatory Body	CDSCO (Central Drug Standard Control Organization)		MDA (Medical Device Authority)	
2	Legal Basis	Drug & Cosmetic Act 1940		Medical Device Act 2012	
3	Assessment of technical data	Notified bodies (NB) Under CDSCO		Conformity Assessment Body (CAB)	
4	Quality system	Schedule M111, ISO 13485		ISO 13485:2016	
5	Registration period	Valid for 3 years		Valid for 5 years	
6	Language	English		English, Bahasa Melayu	
7	Time to approval	6-12 months for the notified device		Approximately 9 months	
8	Market	Emerging Market		Emerging Market	
9	Submission format	Paper / Electronic submission		Electronic submission	
10	Electronic submission	Class	In Rupees One site	Class	In Rupees
		A	81984	A	-
		B	163969	B	82558
		C	245953	C	165116
		D	245953	D	247674

Discussion:

The comparison between medical device regulatory systems in India and Malaysia reveals interesting differences and similarities. Malaysia's medical device regulatory system follows the Global Harmonization Task Force guidelines. GHTF was an international organization that aimed to harmonize medical device regulations worldwide. By adhering to these guidelines, Malaysia aligns its regulatory approach with international standards, facilitating the acceptance of medical devices in the global market. Each country's specific regulations may offer advantages tailored to their healthcare systems and industry needs. India may have specific provisions that encourage domestic manufacturing and innovation, promoting local production and job opportunities. Malaysia's adherence to GHTF guidelines may streamline the process for manufacturers who aim to enter multiple international markets, as compliance with international standards can facilitate global acceptance.

Acknowledgment:
The authors would like to thank the, R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur., for administrative support.

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