



Comparison of Medical Device Regulations in India, Japan and South Korea

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ABSTRACT

Increased health awareness, a growing middle class, and government health efforts are projected to propel India's medical equipment market forward in the next years. With the publication of the Medical Device Rules in 2017, Indian authorities revised the medical device regulatory process. The devices included in the link are currently regulated medical devices and in vitro diagnostic devices, as well as their classifications. CLA (Central Licensing Authority) is in charge of all import device licencing, as well as manufacturing, loan, and wholesale licences for Class C and Class D medical devices.

Because of its complicated registration process and linguistic obstacles, Japan is regarded one of the most difficult markets for overseas medical device producers. The Pharmaceutical and Medical Device Agency, which works in tandem with the MHLW (Ministry of Health and Labour Welfare), is in charge of reviewing drug and medical device applications in Japan. The Pharmaceuticals and Medical Devices Act is a federal law that regulates the sale of pharmaceuticals and medical devices. The Pharmaceuticals and Medical Devices Act, also known as the Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular

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Therapy Products, Gene Therapy Products, and Cosmetics, lays out the current PMDA (Pharmaceuticals and Medical devices Agency) laws in Japan.

South Korea is one of the largest health-care markets in the Asia-Pacific region. Medical Devices in South Korea are regulated by the Ministry of Food and Drug Safety (MFDS), formerly known as the Korea Food and Drug Administration (KFDA). Medical Devices in South Korea are regulated by the Ministry of Food and Drug Safety, formerly known as the Korea Food and Drug Administration. The Medical Device Act of 2015 governs current medical device laws in Korea. To access the South Korean Medical-Device-Market, you must first obtain marketing approval from the local Medical Device Authority, the Medical Device Information & Technology Centre, which is part of the Ministry of Food and Drug Safety. With the MFDS notification No. 2020-29, the South Korean Ministry of Food and Drug Safety launched UDI (Unique Device Identification System) operations in 2018. Article 20 of the Medical Device Act and Article 54-2 of the Medical Device Act Enforcement Regulations make UDI compliance mandatory.

Keywords: *Medical device; regulatory process; registration; amendments; functionalities, classifications; CDSCO (the central drug standard control organisation); KFDA (korea food and drug administration); MFDS (ministry of food and drug safety).*

1. INTRODUCTION

A Medical Device is any device proposed to be utilized for clinical purposes. Medical Device advantage patients by assisting wellbeing with caring suppliers analyze and treat patients and assisting patients with defeating ailment or infection, working on their personal satisfaction. Huge potential for dangers is innate when utilizing a gadget for clinical purposes and hence clinical gadgets should be demonstrated protected and powerful with sensible confirmation prior to controlling governments permit promoting of the gadget in their country. When in doubt, as the related danger of the gadget builds the measure of testing needed to set up security and viability likewise increments. Further, as related danger expands the possible advantage to the patient should likewise increment.

Importance of Medical Device are; Admittance to great quality, reasonable, and suitable wellbeing items is essential to propel general wellbeing inclusion, address wellbeing crises, and advance better populaces.

Without clinical Devices, normal operations – from bounding a hyper-extended lower leg, to diagnosing HIV/AIDS, embedding a counterfeit hip or any careful mediation – would not be conceivable. Clinical gadgets are utilized in numerous assorted settings, for instance, by laypersons at home, by paramedical staff and clinicians in far off centers, by opticians and dental specialists and by medical services experts in cutting edge clinical offices, for anticipation and screening and in palliative

consideration. Such wellbeing advancements are utilized to analyze disease, to screen therapies, to help incapacitated individuals and to mediate and treat sicknesses, both intense and persistent.

2. DISCUSSION

Increased health awareness, a growing middle class, and government health efforts are projected to propel India's medical equipment market forward in the next years. With the publication of the Medical Device Rules in 2017, Indian authorities revised the medical device regulatory process. The Central Drugs Standard Control Organization (CDSCO), an organisation of the Ministry of Health and Family Welfare, regulates devices, which went into effect in January 2018.

In the past, medical gadgets in India were largely uncontrolled. This has shifted in the last year. Medical Devices Rules 2017, as announced by Ministry of Health and Family Welfare Notification No. G.S.R, 78(E) dated 31st January 2017, have come into law with effect from 1st January 2018.

The devices included in the link are currently regulated medical devices and in vitro diagnostic devices, as well as their classifications. The Ministry of Health and Family Welfare will periodically add new devices to this list [1, 2].

The Central Licensing Authority (CLA) and State Licensing Authority (SLA) of India's Central Drug Standard Control Organisation (CDSCO) are responsible for granting licences to import, manufacture for sale or distribution, stock,

exhibit, or offer for sale. CLA is in charge of all import device licencing, as well as manufacturing, loan, and wholesale licences for Class C and Class D medical devices. Manufacturing, Loan, and Wholesale Licenses for Class A and Class B Medical Devices are all handled by SLA.

Only notified medical devices are now controlled as drugs in India under the 1940 Drugs and Cosmetics Act and the 1945 Rules promulgated thereunder.

1. substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood, blood component collection bag with or without anticoagulant covered under sub-clause (i)
2. substances including mechanical contraceptives, disinfectants and insecticides notified under sub-clause (ii)
3. devices notified from time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 [2].

Table 1. Functionalities of CDSCO in accordance with Medical Devices [2]

Functionalities	
Certificate of Registration for Class A and Class B Medical Devices	A National Accreditation Body-accredited notified body may apply to CLA in MD 1 for a registration certificate in MD 2.
Import Licence	Fill out MD-14 on the Sugam online portal to apply for an import licence in MD-15 to bring Medical Devices into the country.
Licence or loan licence to manufacture for sale or for distribution	Fill out an application for Grant of Manufacturing Licence / Loan Licence to Manufacture for Sale or Distribution of Class C or Class D in MD-9 & MD-10 on the sugam web portal in MD-7 & MD-8.
Test licence to manufacture for test, evaluation, clinical investigations, etc.	Fill out an MD-12 application in the Sugam online portal to apply for an MD-13 licence to produce medical devices for clinical research, testing, evaluation, examination, demonstration, or training.
Test licence to import for test, evaluation, clinical investigations, etc.	The applicant must submit an MD-16 application to the sugam online portal for a licence to import Medical Devices for clinical investigations, tests, evaluations, examinations, demonstrations, or training in MD-17.
License to Import investigational medical device by Government hospital or statutory medical institution for treatment of patient	On an application made by a Medical Officer, a small quantity of investigational medical device that is not allowed to be imported but is approved in the country of origin may be allowed to be imported by the Central Licensing Authority for treatment of a patient suffering from a life-threatening disease or disease causing serious permanent disability or disease requiring therapy for an unmet medical need.
Permission to conduct clinical investigation of Investigational Medical Device	Fill an application in MD-22 in sugam online portal for grant of permission to conduct clinical investigation of investigational medical device in MD-23.
Permission to conduct clinical performance evaluation for new in vitro diagnostic medical device	Fill make an application in MD-24 in sugam online portal for grant of permission to conduct clinical performance evaluation of new in vitro diagnostic medical device in MD-25
Permission to import or manufacture medical device which does not have its predicate device	Fill an application in MD 26 in sugam online portal after completion of its clinical investigation to the CLA for grant permission to import or manufacture medical device which does not have predicate medical device in Form MD-27.
Permission to import or manufacture new in vitro diagnostic medical device	Fill an application in MD-28 in sugam online portal for grant of permission to Import or Manufacture for sale or for distribution of new in vitro diagnostic medical device in MD-29.
Registration of Medical	Fill out the MD-39 application in the Sugam online portal to

Functionalities	
Device Testing Laboratory	request that a medical device (MD) testing laboratory be granted registration under MD-40 to test or evaluate medical devices on behalf of the manufacturer.
Application for Issuance of Free Sale Certificate for domestic manufacturers Medical Devices. Application for Issuance of Market Standing Certificate and Non- Conviction for Medical Devices NSQ Verification. Updating the list as per the Classification of Medical Devices from time to time Post Approval Changes in respect of Medical Devices Constitution of MD experts committee. Inspection of manufacturing site for compliance of QMS by CLA/SLA. Capacity building activities of technical management. Preparing and submitting replies of Parliament Questions/RTIs/Clarifications/NOCs/ Port office queries Providing clarification to applicant on the regulatory status of products	

2.1 Classification of Medical Device in India [3,4]

Table 2. Classification of medical devices in India

International Classification	Examples	Risk Level	Type of regulation
Class A	Thermometers, tongue depressors	Low	License not required but voluntarily applied to be licensed by State Licensing Authorities (SLA)
Class B	Hypodermic needles, suction equipment	Low Moderate	Approval by the SLAs
Class C	Lung ventilator, bone fixation	Moderate High	Approval by Central
Class D	Heart valves, implantable devices	High	Licensing Authority (CLA)

2.2 Premarket Approval Process in India [3, 4]

Table 3. Premarket approval process of medical devices in India

Class A	Class B	Class C	Class D
Self-regulation	Approval by SLA	Approval by CLA	
Application for registration (appoint an authorized Indian agent)			
Registration certificate issued by CDSCO			
Application for import license			
Import License issued by CDSCO			

2.3 How to Register a Medical Device in India: A Step-by-Step Guide

Manufacturers used to be able to sell medical gadgets in India without any restrictions. Since 2006, medical devices entering India have had to comply with the CDSCO's Indian Medical Device Regulations. The CDSCO is in charge of approving and regulating new drugs and clinical trials in the country, as well as establishing drug standards, monitoring the quality of imported drugs, coordinating the activities of state drug control organisations, and providing expert advice in order to ensure that the Drugs and Cosmetics Act is enforced uniformly.

The procedure for registering your medical device in India is outlined below;

Step 1: Determine if your product needs to be registered.

The Drugs and Cosmetics Act, 1940, and its Rules, 1945, govern the import, manufacture, sale, and distribution of medical equipment in India. Currently, the aforementioned Act regulates 22 Notified Medical Devices. Spinal needles, cochlear implants, annuloplasty rings, tracheostomy tubes, syringes, and needles are all medical devices that must be registered in India. Surgical sealants, dental implants, heart valves, cardiac stents, orthopaedic implants, endotracheal tubes, and catheters are just a few examples. The CDSCO should be contacted about registering these devices (Documents required to register your medical device in India). These devices aren't the only ones on the list. In some situations, the DCGI will analyse product information and issue a NOC, which is an exemption from the medical device registration process. This procedure might take anything from 4 to 12 weeks.

Step 2: Select an Indian Agent who is authorised to represent you (Authorized Indian Agent).

Foreign producers must have a representation in India to function as a point of contact for inspection authorities, aid with device approvals and registration, and report vigilance adverse events, according to Indian regulations.

An authorised Indian agent can be appointed by a manufacturer to register with the CDSCO on their behalf. The Indian Agent will serve as a point of contact between you and the Medical Devices Division of the CDSCO. A wholesale

drug licence in the range of 20B and 21B should be held by the authorised Indian agent. The manufacturer will be the owner of the registration certificate and will be able to appoint as many distributors as they like around the country [5, 6, 7].

Step 3: Fill up Form 40 and submit the Regulatory Dossier.

To begin the registration process, a dossier with the requisite list of papers must be completed. The following is a list of the documents that must be submitted.

- Form 40
- TR6 Challan
- Power of Attorney
- Schedule D (1)
- ISO 13485 Certificate,
- Full Quality Assurance Certificate
- CE Design Certificate
- Declaration of Conformity
- Free Sale Certificate
- Certificate of Marketability from GHTF countries
- Other Regulatory Approvals
- PMS report

2.4 Amendments to the Medical Devices (Amendment) Rules, 2020

The Indian law that governs the quality and safety of medical devices has been updated, and it now applies to all medical devices as of April 1, 2020. Only 37 kinds of medical devices were regulated or were notified to be regulated in the near future in India prior to the modification.

The following are the immediate effects of the legislative change:

- Before October 1, 2021, all currently unregulated medical devices must be registered with the Drugs Controller General of India by their respective importers or makers. Medical devices that are already regulated or have been notified to be regulated, on the other hand, are excluded from the registration requirement (see list of 37 categories of medical devices at the end of this article which are exempt from registration).
- Importers, makers, distributors, whole sellers, and retailers of currently

unregulated Class A (low-risk) and Class B (low-medium risk) medical devices selling in India will be required to obtain a licence by August 11, 2022.

- Importers and manufacturers, distributors, whole sales, and retailers of currently unregulated Class C (medium-high risk) and Class D (high risk) medical equipment selling in India will be required to obtain a licence by August 11, 2023.

Importers and manufacturers of medical devices must be certified as compliant with ISO-13485 in order to get registration.

The Government of India published two notifications on February 11, 2020: a revised definition of medical devices and The Medical Devices (Amendment) Rules, 2020. The combined consequence of these two notices is that all medical devices will be subject to quality and safety regulation as of April 1, 2020, the effective date of both notifications [2,8].

2.5 To Import Medical Devices into India

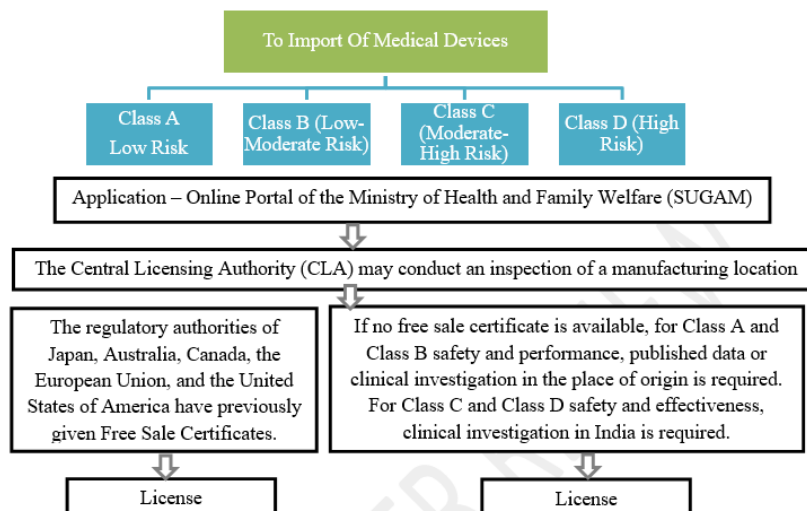


Fig. 1. Procedure for import of medical devices into India

2.6 To Manufacture Medical Devices for Sale or For Distribution in India

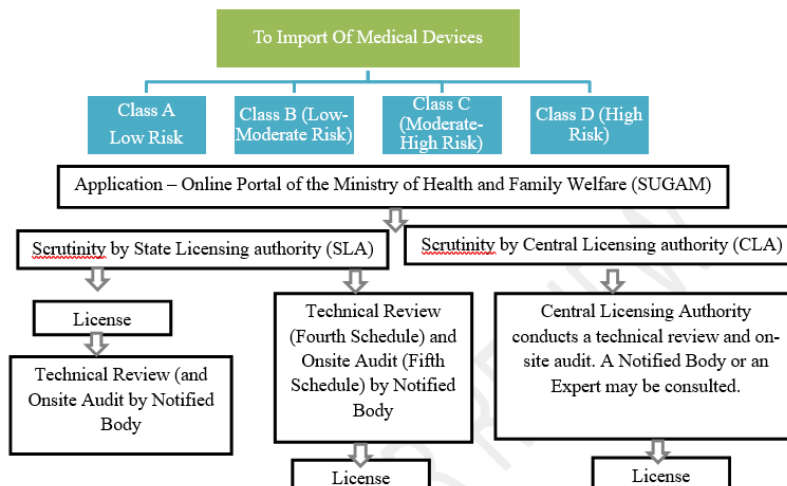


Fig. 2. Process for grant of license to manufacture medical devices in India

JAPAN

Contents

1. Introduction
2. Classification
3. PMA
4. Regulatory requirements & approval process
5. Registration Process
6. Import Process

Because of its complicated registration process and linguistic obstacles, Japan is regarded one of the most difficult markets for overseas medical device producers. However, after you grasp the device registration procedure, you'll discover that it's not as difficult as it appears, and the benefits are well worth the effort. Japan's lucrative medical device sector is the world's second largest, trailing only China and Germany. The Ministry of Health, Labor, and Welfare (MHLW) of Japan is the regulatory organisation in charge of overseeing food and medications in the country, as well as developing and enforcing safety standards for medical equipment and drugs. The Pharmaceutical and Medical Device Organization (PMDA) is an independent agency that reviews drug and medical device applications in collaboration with the MHLW. The

PMDA collaborates with the MHLW to evaluate new product safety, formulate detailed regulations, and monitor product safety once it has been released.

The Pharmaceuticals and Medical Devices Act (PMD Act) is a federal law that regulates the manufacture, distribution, and sale of pharmaceuticals and medical devices. The Pharmaceuticals and Medical Devices Act (PMD Act), also known as the Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, lays out the current PMDA laws in Japan. All areas of Japanese medical product registration are affected by the PMD Act, including in-country representation, certification processes, licencing, and quality assurance systems. The Pharmaceutical Affairs Law was repealed by the PMD Act, which took effect on November 25, 2014. (PAL). The laws include the following features:

- Some Class III medical equipment can be certified by a third party
- Medical software applications are governed independently
- Manufacturers must register rather than be licenced [1,2,5].

2.7 Classification of Medical Device in Japan

Table 4. Classification of Medical Devices in Japan [3,9]

Internati onal Classific ation	Risk base Medical Device Classific ation	Classific ation	Risk Level	Type of regulation
Class I	Devices with extremely low risk to the human body in case of problems	General Medical Device	Extremely low	Approval/certification not required (Notification/self-declaration)
Class II	Devices with relatively low risk to the human body in case of	Controlled Medical Device	Low	Certification by third party certification

International Classification	Risk base Medical Device Classification	Classification	Risk Level	Type of regulation
Class III	problems Devices with relatively high risk to the human body in case of problems	Specially Controlled Medical Device	Medium / High	
Class IV	Devices highly invasive to patients and with life-threatening risk in case of problems			Approval by the MHLW

2.8 Premarket Approval Process in Japan

Table 5. Premarket Approval Process for Medical devices in Japan [3,9]

Class I	Class II(Specified-Controlled)	Class II(Controlled)	Class III	Class IV
Notification by PMDA	Certification by Registered Certified Body (RCB)	Approval by MHLW		
Application for product notification to PMDA	Application for product verification to RCB	Summary Technical Document (STED) to PMDA		
Quality Management System (QMS) requirement submission to PMDA or RCB				

2.9 The PMDA's regulatory requirements and approval process for medical devices in Japan

(generic/proprietary), intended use, shape, structure, and so on.

Class I Device Regulations:

Todokede is the name of the approval process for Class I Devices.

The following are some of the requirements for class I medical device approval: category, name

The approval procedure begins with the MAH filing a notification, and this kind of medical device may not need to be assessed by the PMDA.

The PMD Act and the Ministry of Health, Labour, and Welfare must be followed, and the Quality Management System (QMS) must be used

(MHLW). Manufacturing facilities, on the other hand, must be registered.

Regulatory for Class II Devices

The Ninsho approval process is used for Class II Devices.

Details about the intended purpose, proprietary name, shape, structure, direction for use, manufacturing procedures, storage conditions, and shelf life, among other things, are required documents for class II medical device registration.

- A notarized body must be used to start the application by the MAH. Certain class II devices may necessitate both PMDA and MHLW reviews.
- A second level of approval may be required by the overseas producer.
- This type of medical gadget also necessitates the upkeep of a Quality Management System (QMS).

Timelines vary from 4 to 9 months depending on the thoroughness of the application and other considerations.

Regulatory for Class III & Class IV Devices:

Shonin (approval process for Class III and Class IV devices) is a term used to describe the approval procedure for Class III and Class IV devices.

- With a few exceptions, the applications for Class III and Class IV are nearly identical. This procedure also applies to medical equipment classified as Class II Controlled.
- The PMDA receives the application and conducts a QMS conformity assessment inspection at the production facility.

General requirements, such as medical device category, intended use, efficacy risk analysis data, clinical data, and so on, are included in the application requirements. In addition, there are attachments such as a technical documentation summary (STED).

The length of time it takes for an application to be approved depends on the device's class and the sort of approval method used [9,8,6].

2.10 Medical Device Approval Process in Japan

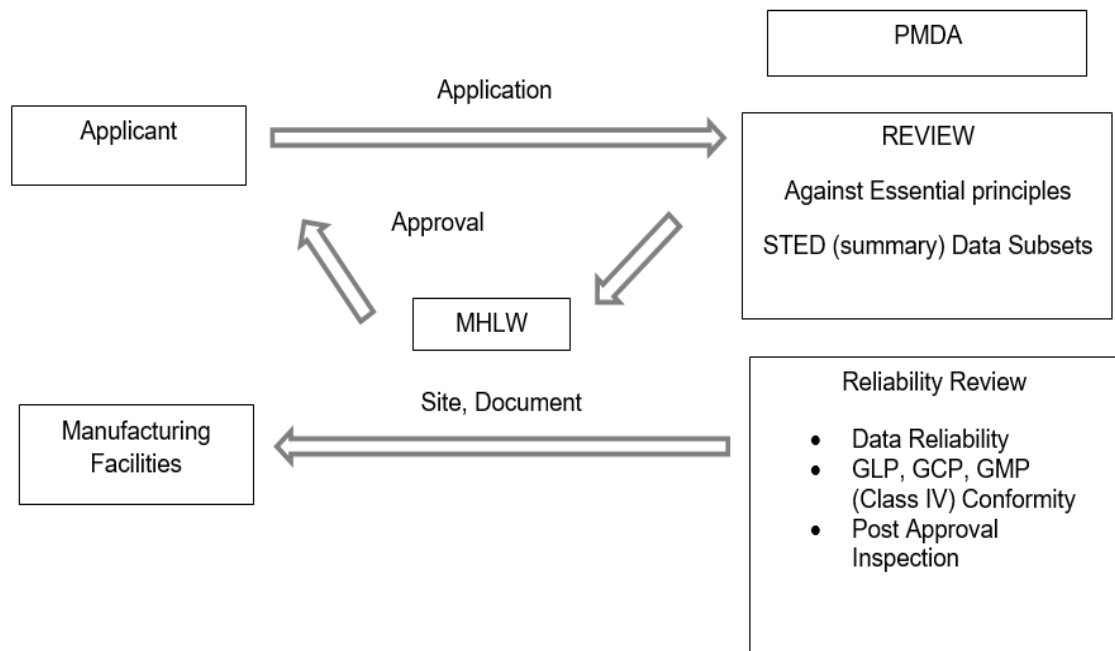


Fig. 3. Medical device approval process in Japan [9]

2.11 Process of Importation

The present Japanese Import Notification criteria for foreign medical equipment and medications registered for sale in Japan ended at the end of 2015, and a new importation system took effect on January 1, 2016.

Medical device makers' Marketing Authorization Holders (MAH) or Designated Marketing Authorization Holders (D-MAH) would be required to provide copies of their MAH licences to customs officials for clearance, according to an announcement by Japan's Ministry of Health, Labour and Welfare (MHLW).

Copies of premarket approvals, premarket certifications, or premarket submissions must also be supplied to customs officers for devices already registered for sale in Japan. MAHs and D-MAHs must also submit copies of premarket approval, certification, or submission applications bearing receipt stamps from either the PMDA or a Registered Certification Body (RCB) for unregistered devices under review by the Pharmaceuticals and Medical Devices Agency (PMDA) or a Registered Certification Body (RCB).

Foreign medical device companies selling in Japan should double-check that their D-MAH partners are aware of the new import notification requirements.

A whitepaper on the Pharmaceutical and Medical Devices Law and a process chart on the country's device approval process are among the other Japanese regulatory resources available from Emergo [8, 10, 11].

SOUTH KOREA

Contents

1. Introduction

2. South Korea Medical Device Classification
3. Pre-Market Approval Process
4. Medical Devices Regulation
5. Device Registration
6. Post approval

3. INTRODUCTION

South Korea is one of the largest health-care markets in the Asia-Pacific region. Medical Devices in South Korea are regulated by the Ministry of Food and Drug Safety (MFDS), formerly known as the Korea Food and Drug Administration (KFDA). The Medical Device Act (MDA) of 2015 governs current medical device laws in Korea. To enter the South Korean medical device market, you must first obtain marketing authorisation from the Medical Device Information & Technology Centre (MDITAC), which is part of the Ministry of Food and Drug Safety (MFDS).

With MFDS notification No. 2020-29, the South Korean Ministry of Food and Drug Safety (MFDS) commenced UDI operations in 2018. Article 20 of the Medical Device Act (No. 14330) and Article 54-2 of the Medical Device Act Enforcement Regulations make UDI compliance mandatory (No. 1512). To market a medical device in South Korea, you must first register with the Integrated Medical Device Information System (IMDIS). For Class II, the next mandate for UDI reported and on-label compliance is due in September 2021. For Class III, track and trace requirements are expected in July 2021.

The South Korean Ministry of Food and Drug Safety (MFDS), which is in charge of medical device regulation, has released a pamphlet that gives an overview of the current regulatory system. The document addresses the most significant features of medical devices, such as the introduction of a new product to the market, registration revisions, and post-market surveillance [1,2].

Table 6. Overview of South Korea regulatory [3]

Regulatory Authority	Ministry of Food and Drug Safety (MFDS)
Regulation	Medical Device Act (MDA) 2015
Authorized Representative	Malaysian Representative required
QMS Requirement	ISO 13485:2016
Assessment of Technical Data	Third party certifying bodies
Validity of License	Does not expire
Labeling Requirements	Ministerial Decree No. 18, Art. 28.
Submission Format	Online
Language	Korean

3.1 Medical Device Regulation in South Korea: A National Approach

The regulatory framework in place in South Korea for medical devices meets the industry's highest worldwide requirements. There are four levels of legislation that control all medical device operations:

1. Medical Device Act,
2. Presidential Decree on Enforcement,
3. Prime Minister's Order on Enforcement, and
4. MFDS Notifications (ordinance of Minister of MDFS).

South Korea has a harmonised risk-based classification system for medical devices that adheres to the principles put forth by the International Medical Device Regulators Forum (IMDRF), a non-profit organisation of national regulatory agencies working together to enhance medical device regulation. The country has already enacted criteria relating to the manufacturer's Quality Management System (QMS) (harmonised with ISO 13485) and clinical trials (harmonized with ISO 14155).

The authority also announced the installation of the Unique Device Identification (UDI) system, which will improve the exchange of medical device information. UDI would be implemented in the following ways, depending on the specific class in accordance with the risk-based classification:

- Class 4 (high-risk) medical devices – already implemented in July 2019;
- Class 3 (significant risk) medical devices – to be implemented in July 2020;
- Class 2 (moderate risk) medical devices – to be implemented in July 2021;
- Class 1 (lowest risk) medical devices – to be implemented in July 2022. [3, 4, 5]

3.2 Medical Device Classification in South Korea

Devices in South Korea are categorised into Class I, II, III, and IV based on their risk level, according to the MFDS Notification No. 2016-4. Patients are at low risk with Class I devices, but Class IV devices are high-risk, sophisticated equipment. The MDITAC requires certification for Class I and some Class II devices, while the MFDS requires permission for new Class II, Class III, and Class IV devices.

Table 7. Medical device classification in South Korea [3]

International Classification	Risk base Medical Device Classification	Risk Level	Type of regulation
Class I	Devices with extremely low risk to the human body in case of problems.	Little	Approval/certification not required (Notification/self-declaration)
Class II	Devices with relatively low risk to the human body in case of problems	Low	Certification by Medical Device information and Technology Assistance Center. (MIDTAC) Approval by the National Institute Food and Drug Safety. (NIFDS)
Class III	Devices with relatively high risk to the human body in case of	Moderate	Approval by the

International Classification	Risk base Medical Device Classification	Risk Level	Type of regulation
Class IV	problems Devices highly invasive to patients and with life-threatening risk in case of problems	High	NIFDS

3.3 Pre-Market Approval Process in South Korea

Table 8. Pre-Market Approval Process in South Korea [3]

Class I	Class II(Modified & Equivalent)	Class II(New)	Class III	Class IV
Notification by MIDTAC	Certification by MIDTAC	Approval by NIFDS		
KRW 35,000 + Application for product notification	5 days, KRW 42,000 + Application for product verification	10 days, KRW 402,000 + Summary Technical Document (STED) by 3rd party 55 days for STED, 70 days for Clinical report KRW 1,400,000 +		
Quality Management System (QMS) requirement submission to MIDTAC or NIFDS				

3.4 Medical Devices Regulation in South Korea

The Medical Device Act (MDA), which took effect in 2004, governs medical device laws in Korea. Since its first release, the MDA has been amended and modified several times. The MFDS issues appropriate notices on a regular basis that address more specific technical criteria for manufacturers and importers.

In-Vitro Diagnostic (IVD) medical devices are subject to specific restrictions under South Korean medical device legislation. It comprises, in particular, risk-based classification and simultaneous examination of both the device and the medicine for which it was designed. The registration path to be used is determined by the device's risk-based classification in South Korea.

1. Class I (lowest risk) medical devices should be subject to notification procedure registration;
2. Class II (moderate risk) medical devices with a substantial equivalent (similar medical device already on the market,

SE) must meet the conformity requirements and obtain the appropriate certification.

3. Medical devices in Class II that have no substantial equivalent (entirely new medical devices, NSE), as well as Class III and IV medical devices, should be reviewed and approved.

It's also worth noting that the MDFS is solely responsible for Class II NSE, Class III, and Class IV medical devices, while the National Institute of Medical Device Safety is in charge of Class I and Class II SE medical devices (NIDS).

The MDFS issues special guidance documents dedicated to the most important aspects of the requirements and regulatory procedures to be performed when placing the device on the market in order to assist medical device manufacturers and other parties involved in maintaining compliance with applicable safety and performance requirements. The requirements for medical device makers to be authorised to offer their equipment on the market include, among other things, the Quality

Management System standards. The manufacturer's QMS should, in particular, conform with national regulations based on the international standard ISO 13485. On-site audits should be necessary for producers of Class II, III, and IV medical devices, while such audits should be optional for makers of Class I medical devices. QMS Audit Institutions, which are independent bodies properly designated by the authority, should conduct such audits.

The audit shall be carried out on the manufacturer's request, which should be given in the form of an application, and in coordination with the MFDS auditor. The QMS Audit Institution has the authority to issue the QMS certificate, to require the manufacturer to make certain corrections, or to notify the manufacturer of the prohibition of distribution due to a major nonconformity or if the minor nonconformities identified during the audit have not been corrected upon the Institute's appropriate request.

The audit could be for a variety of reasons, depending on the goal:

- An initial audit to ensure QMS compliance,
- A periodic audit performed at least once every three years after the original audit,
- An audit to approve modifications to manufacturing locations as reported by the manufacturer, and
- A supplementary audit performed if a product from another group is added. The publication released by the MFDS summarises the information presented above and covers the most significant areas of medical device regulation in South Korea [6, 7].

3.5 Korean Licence Holder (KLH)

To become a licence holder in Korea, a company must have a registered business address and a full-time quality manager. Without a recognised local business office, foreign producers must appoint a License Holder in Korea to submit Medical Device registrations to the MFDS.

KGMP (Good Manufacturing Practice) Certification: Korea Good Manufacturing Practice (KGMP) quality system criteria must be met by both the manufacturer and the Korea License Holder. An on-site audit of overseas manufacturing plants is part of the KGMP

certification process. The MFDS issues the KGMP certificate, which is valid for three years. Before you can apply for a job, you must first obtain certification [8].

3.6 Registration of Devices in South Korea

The procedure for registering a gadget differs depending on the type of device.

Medical Devices of Class I:

The majority of Class I medical devices are excluded from technical review and KGMP certification procedures, and they require a Pre-Market notification to be marketed. The manufacturer must supply basic device details and submit an application for approval. After uploading registration information to the MFDS portal, the registration of a Class I device will be completed.

Class II, III, and IV devices:

Class II, III, and IV device manufacturers must get pre-market approval, and the registration does not expire. The devices can be approved by the MFDS using any of the two review options below:

- Technical File Review in General
- Review of technical safety and efficacy (SER)

Although clinical study results are not necessary for General Technical File Review, they are required for Technical SER. The MFDS reviews the General Technical File or SER Technical File for classes other than Class I.

3.7 Post Approval

- Post-approval change management - alterations to existing Medical Device approvals such as the inclusion of new versions, accessories, and indications of use, among other things.
- Renewal of licences
- Liaising between the MFDS and the manufacturer
- Importation Management
- Maintenance of permissions and registration through prompt payment of administrative and registration fees [9, 10].

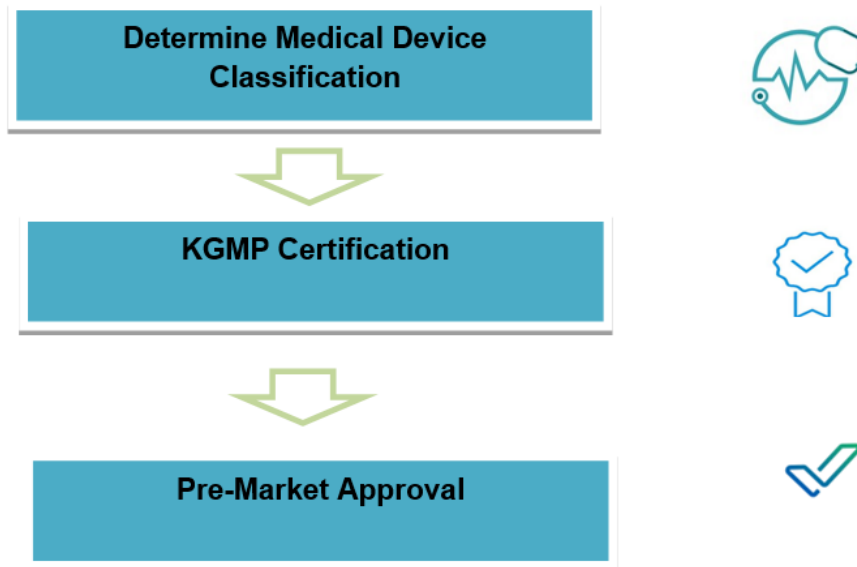


Fig. 4. Process flow for registration of medical devices in South Korea [9]

4. CONCLUSION

The Ministry of Health and Family Welfare, The Central Licensing Authority (CLA) and State Licensing Authority (SLA) of India's Central Drug Standard Control Organization (CDSCO) are answerable for conceding licenses to import, produce available to be purchased or conveyance, stock, display, or make available for purchase. Assembling, Loan, and Wholesale Licenses for Class A and Class B Medical Devices are completely dealt with by SLA.

In light of its convoluted enlistment measure and phonetic obstructions, Japan is respected perhaps the most troublesome business sectors for abroad clinical gadget makers. The Ministry of Health, Labor, and Welfare (MHLW) of Japan is the administrative association responsible for managing food and meds in the nation, just as creating and authorizing wellbeing norms for clinical devices and medications.

The Medical Device Act of 2015 oversees current Medical Devices laws in Korea. The Medical Device Act Enforcement Regulations make UDI consistence compulsory. The archive tends to the main highlights of medical devices, like the acquaintance of another item with the market, enlistment updates, and post-market surveillance.

The Pharmaceuticals and Medical Devices Act, otherwise called the Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy

Products, Gene Therapy Products, and Cosmetics, spreads out the current PMDA laws in Japan. Clinical Devices in South Korea are directed by the Ministry of Food and Drug Safety, once in the past known as the Korea Food and Drug Administration. To join the South Korean MDR market, promoting authorisation from the nearby Medical Device Authority, Medical Device Information and Technology Center, which works under the Ministry of Food and Drug Safety, is required.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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