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Medical Device Registration in South Korea

Regulatory requirements, technical document preparation, and more



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Korea's Medical Device Regulatory Structure - Introduction

South Korea first introduced the Medical Device Act in 2003 to protect the public from unsafe devices and serve the interests of many different groups, from politicians to industry organizations. The Ministry of Food and Drug Safety (MFDS) amended the law several times since its introduction to harmonize with global standards. Many manufacturers encounter difficulties when entering the Korean medical device market. This is due in part to language and cultural differences, as well as cumbersome registration requirements, such as onsite QMS audits. Yet, Korea is a strategically significant and profitable market. Foreign manufacturers can overcome these obstacles and navigate the regulatory process with the help of a local expert.

The objective of this whitepaper is to help foreign manufacturers understand the regulatory process in Korea, and to illustrate the required steps to register your medical device. This paper provides a high-level overview of registration requirements for medical devices only, although many areas apply to in vitro diagnostic (IVD) device manufacturers as well.

Korea's medical device regulatory structure

Medical devices and IVDs in South Korea are regulated by the MFDS. The South Korean medical device regulatory framework is based on the Medical Device Act, Enforcement Decree of the Medical Device Act, the Enforcement Regulation of the Medical Device Act, as well as other corresponding regulations. Requirements for medical devices are outlined in detail in the Regulation for Approval, Notification, and Review of Medical Devices, and the Regulation on Korea Good Manufacturing Practices (KGMP). These and other relevant regulations can be found on the MFDS website.

Key players within the MFDS

The MFDS is composed of its headquarters, the National Institute of Food and Drug Safety Evaluation (NIFDS), and six Regional Food and Drug Administration offices. The MFDS headquarters has seven bureaus as illustrated in Figure 1. The Medical Device Safety Bureau is responsible for regulating medical devices and comprises three divisions: the Medical Device Policy Division, the Medical Device Management Division, and the Medical Device Safety Evaluation Division.

The Medical Device Policy Division oversees the establishment and revision of medical device regulations, classification, policy, and other related issues. The Medical Device Management Division manages post-market surveillance and vigilance. Finally, the Medical Device Safety Evaluation Division manages safety-related tasks, such as adverse event management, traceability, and radiation safety.

Korea's Medical Device Regulatory Structure

Figure 1 (Source: MFDS)

Korea's Medical Device Regulatory Structure

The NIFDS is responsible for "science-based risk assessment, review/evaluation and approval, and research on food and medicinal products." Within the NIFDS, the Medical Device Evaluation Department reviews Technical Documents for medical device registrations and approvals. Submissions are assigned to one of five divisions depending on the device type:

- High-tech medical devices division: responsible for new technology
- Cardiovascular devices division
- Orthopedic and restorative division
- Dental and gastroenterology device division
- In-vitro diagnostic division

The MFDS publishes the contact information of all divisions, as well as associated reviewers on its public websites. This allows industry to anticipate which division will review submissions made to the MFDS.

A breakdown of the NIFDS is as follows:

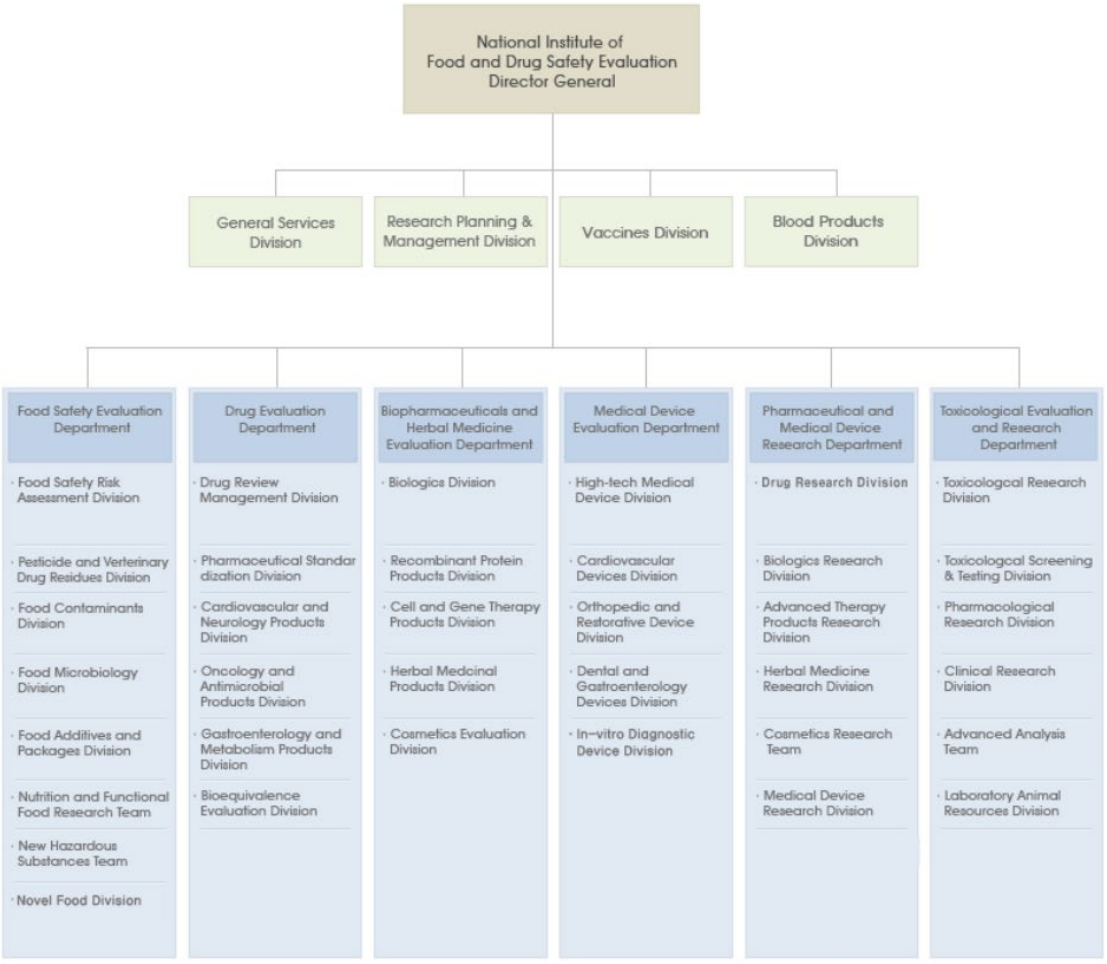


Figure 2 (Source: NIFDS)

The path to commercialization in Korea includes three main steps: Korean Good Manufacturing Practice (KGMP) quality system certification (for class 2 and above), device registration, and reimbursement pricing assessment (as applicable).

KGMP certification is required for medical device and IVD manufacturers of Class 2, 3, and 4 devices. KGMP certification requires the preparation of a detailed application, followed by an on-site quality system audit of the manufacturing site(s). KGMP is harmonized to ISO 13485:2003, but manufacturers must address additional Korean requirements, such as post market surveillance and reporting requirements. An ISO 13485:2003 certificate cannot be substituted for an onsite KGMP inspection. Class 1 device manufacturers are exempt from the KGMP certification requirement.

Next, any medical device or IVD should be registered with the MFDS. The registration requirements depend on the device classification, type, and identification of a substantially equivalent device in Korea. These requirements are explained in more detail on the following pages.

The final steps in the process include a reimbursement pricing determination by the Health and Insurance Review Assessment Service (HIRA), followed by a Ministry of Health & Welfare (MoHW) review. If the device in question uses new health technology dissimilar to other products registered on the HIRA reimbursement/non-reimbursement list, that device should go through a New Health Technology Assessment (NHTA) before beginning the application for reimbursement determination. Reimbursement is a major consideration in Korea, since over 95% of the population is covered through the public healthcare system. However, this white paper focuses on other aspects of the regulatory process.

In-country representation for foreign manufacturers: Korea License Holder

Prior to beginning the registration process, manufacturers without an entity in Korea must enlist an in-country representative, known as a Korea License Holder (KLH), to manage the application submission and maintenance on their behalf.

KLHs must comply with a number of requirements, including:

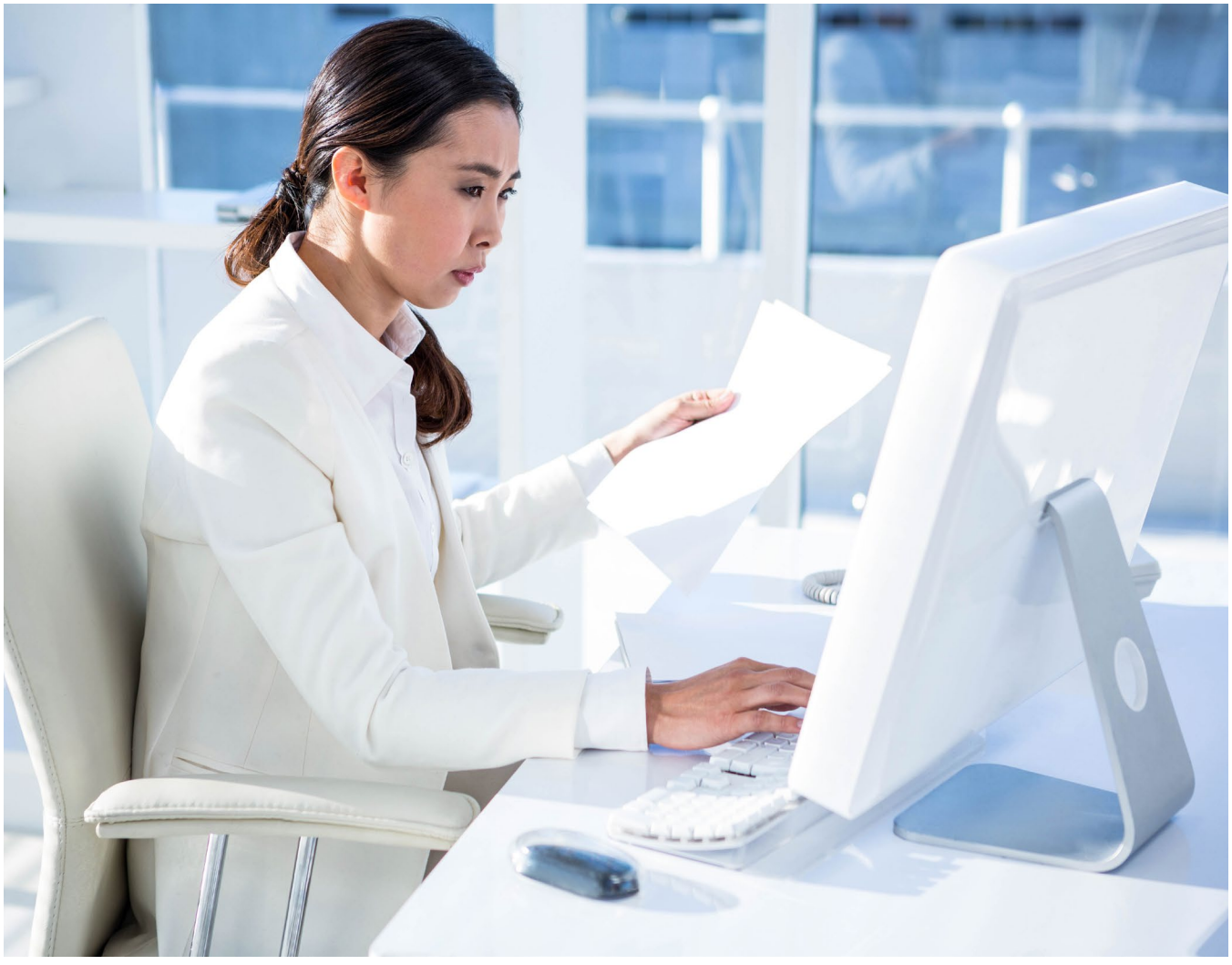
- the employment of a certified Quality Manager,
- possession of an Import Business License,
- and ongoing maintenance of KGMP certification specific to the device category(-ies) they represent.

Further, the KLH (also known as an In-country Caretaker, or ICC) must be involved in each importation to perform a quality control check and “release” the product into the market. These responsibilities are similar to the responsibilities of an MAH/D-MAH (Market Authorization Holder/Designated Market Authorization Holder) in Japan. For this reason, many KLHs are also distributors.

However, companies that prefer to limit a distributor's control of their product in Korea can appoint an independent representative as their KLH. The representative will either provide the full KLH support described above, or provide license holding services only. Firms that provide full KLH support must handle customs clearance and inspection, including taking possession of the products, purchasing them from the manufacturer, and reselling them to the distributor. These companies often take a commission per shipment.

The other option is to appoint an independent KLH as a license holder only. This option eliminates the KLH's involvement in the importation process; however, each subsequent distributor must procure a registration certificate in their name in order to import. Rather than going through the full registration process, distributors can leverage the first KLH's certificate to obtain an Identical Registration Certificate (IRC). This process requires that both KLHs have access to the complete registration file and detailed technical information.

The Identical Product Registration can usually be obtained within 1-2 months. The license holding service is comparable to insurance for the manufacturer, so they are not removed from the market if their relationship with their distributor falls through.



Medical Device Definitions

The medical device definition offered in Article 2 of the Medical Device Act is similar to those used by the European Union and the former Global Harmonization Task Force. Interpretation follows:

The term "medical device" means an instrument, machine, device, material, or any other similar product specified in the following subparagraphs as one used, alone or in combination, for human beings or animals:

1. *A product used for the purpose of diagnosing, curing, alleviating, treating, or preventing a disease;*
2. *A product used for the purpose of diagnosing, curing, alleviating, or correcting an injury or impairment;*
3. *A product used for the purpose of testing, replacing, or transforming a structure or function;*
4. *A product used for birth control.*

Additionally, the MFDS defines several subsets of medical devices in the Medical Device Approval Regulations, as follows:

- *"A Medical Device Combination" means two or more medical devices combined into one medical device, which exercises combined functions.*
- *"A Medical Device Kit" means two or more medical devices in one packing unit.*
- *"Advanced Medical Device" means a new type of medical device based on innovative scientific technology such as biotechnology, information technology, nanotechnology or robot technology, and fusion medical devices.*
- *"Part" means a necessary part to compose the main body of a medical device.*
- *"New Product" means a medical device whose purpose of use, principle of action, and raw material (only for medical supplies) are not identical to the already approved or certified medical device.*
- *"Improved Product" means a medical device whose purpose of use, principle of action, and raw material (only for medical supplies) are identical to the already approved or certified medical device, but performance, test specification, and method of use are not identical to that product. Note: for IVDs, this definition pertains to a product whose purpose of use and principle of action are identical to those of an already approved or certified device, but raw material or performance are not identical to it.*
- *"In-Vitro Diagnostics Device" means a reagent using a clinical specimen derived from the human body for examination, outside the body, intended to provide information for diagnosis of disease, prognosis observation, judgement of blood or tissue compatibility, etc. Note: preparation reagents prepared in the lab are exempt.*
- *English translations of definitions are published by the Korea Medical Device Industry Association (KMDIA), but their accuracy as legal definitions is not guaranteed. The PDF version of the translation is available on the KMDIA website.*

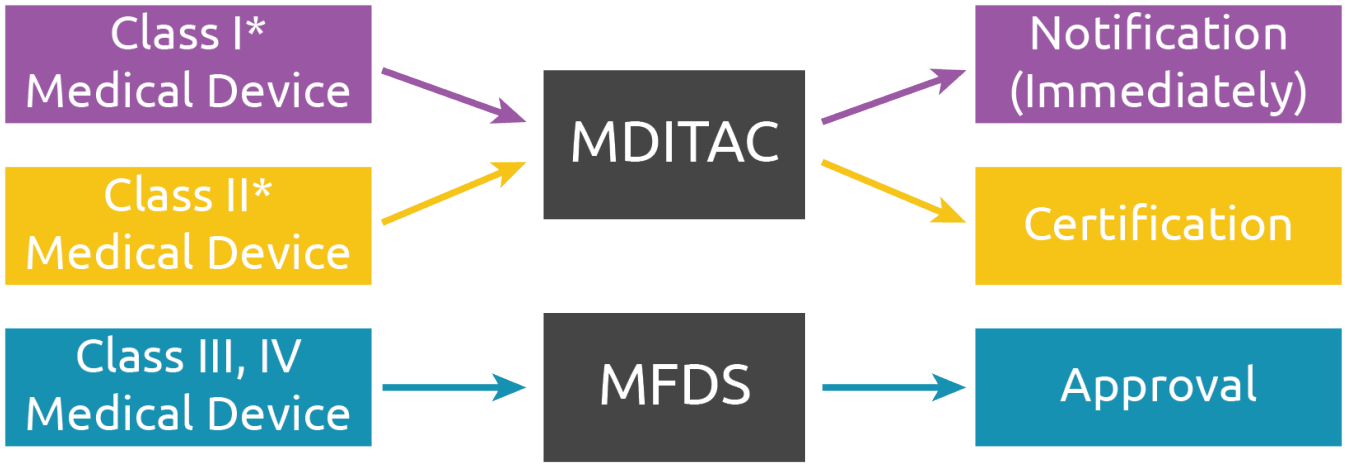
MFDS Medical Device Classification

Device classification rules and procedures are defined in the Enforcement Regulations of the Medical Device Act, Article 2 and corresponding Table 1. The South Korean classification system, list of device categories, and corresponding classifications are specified in the Regulations for Product Classification of Medical Device and Class by Product ("Medical Device Classification Regulation").

The MFDS uses a four-tiered classification system based on risk to the human body. Increasing risk is assigned to Class I, II, III, and IV devices, respectively. The system is also similar to the US Food and Drug Administration (FDA) classification system in that each device is individually assigned a product code. Unlike the FDA's web-based classification database, the MFDS publishes a classification file that includes medical device descriptions, corresponding classifications, and categorization. The file is updated with new product codes on an ongoing basis; as of this printing, the latest version is 2017-6, which was published on January 24, 2017.

Registration pathways and technical documentation requirements by classification

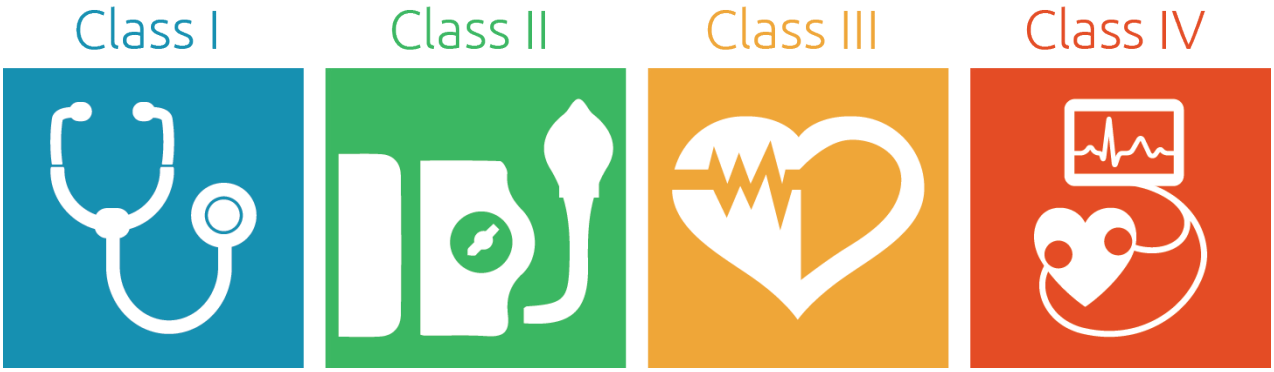
The device classification and availability of a suitable predicate determines the registration pathway in Korea. An overview of the possible pathways is as follows:



*Class I and II devices without a suitable predicate in Korea require Approval from the MFDS.

Class I devices require notification only, and applications are submitted electronically to the Medical Device Information & Technology Assistance Center (MDITAC). MDITAC is a review agency accredited by the MFDS to review low-risk applications.

While the notification process is similar to the US FDA's Class I listing system, manufacturers have to provide more information about their device and technology for a Class I Korea notification application. However, they do not have to submit test reports or a KGMP certificate.



Source: Emergo

Class II-IV manufacturers must prepare an application file with supporting Technical Document Attachments. Class II devices are certified through MDITAC, although companies can engage an MFDS-designated Third Party Reviewer (TPR) for the application review. There are six approved TPRs, four local companies, and two international (SGS Korea and TUV SUD Korea). The TPRs are independent commercial entities, and companies can benefit from a faster review and approval when a TPR is engaged. MDITAC also conducts technical reviews for companies who do not want the additional cost of a TPR.

Class III and IV devices require approval through the MFDS; further, Class IV manufacturers must submit a technical file in Summary Technical Documentation (STED) format. The STED submission should be prepared in Korean; appendices, such as test reports and risk management files, may not require translation. Requirements for STED are more rigorous compared to lower-risk device submission dossiers.

All Class II-IV applications must include a table showing comparison to a substantially equivalent device registered with the MFDS. Devices without a predicate on the South Korean market require clinical data, and will go through an elevated review known as Clinical Data Review (CDR). CDR applications have the most robust technical file requirements, including post-market data, information about how the device is used in other markets, and the scientific background behind research and development.

What Is Required for an MFDS Registration Submission?

Registration submissions can be sent electronically or by mail in a printed form. However, the MFDS prefers electronic submissions. The MFDS posts updates on the progress of your review online, which your KLH can access by logging into the MFDS website. As mentioned, registration submissions are composed of two main parts: the application and the technical document attachments. (Requirements for IVD submissions are very different.)

Medical Device Registration Application

The required items in the product registration application are described in the Article 7 of the Regulation for Approval, Notification, and Evaluation of Medical Device, MFDS Notification No.2016-132. An approximate translation of these items is as follows:

1. **Approval (Class III & IV) and certification (Class II) application:**
    i. Name (product name, category name, model number)
    ii. Category number (Classification)
    iii. Appearance and configuration
    iv. Raw material (devices containing mercury, asbestos, or phthalates cannot be registered in Korea)
    v. Method of manufacture (The applicant shall write "according to manufacturer's manufacturing method" and provide method of sterilization, if applicable. Class IV devices shall provide detailed methods of manufacture.)
    vi. Intended use
    vii. Method of use
    viii. Cautions
    ix. Packaging unit
    x. Storage condition and shelf life
    xi. Test standard
    xii. Manufacturer (in case of importation or contract manufacture of entire manufacturing process)
    xiii. Approval (certification) condition
    xiv. Remarks

2. **Notification (Class 1) application;**
    i. Name (product name, category name, model number)
    ii. Category number (Class)
    iii. Appearance and configuration
    iv. Intended use
    v. Method of use
    vi. Cautions
    vii. Manufacturer (in case of importation or contract manufacture of entire manufacturing process)
    viii. Remarks

Article 9 of the Enforcement Regulation of the Medical Device Act, No. 1389 describes requirements for the body of the Technical Documentation and attachments (appendices). The MFDS requires specific information about your device that must be submitted in Korean. To help clarify their requirements, the agency provides numerous guidelines and technical documentation samples through its website and publications. In Article 9, MFDS specifies seven items required in the medical device application. (Again, requirements are different for IVDs.)

1. The comparison between subject device and predicate device
2. Intended use statement
3. Mode of action (device description)
4. Test reports (if applicable)
    - Electrical/mechanical safety
    - Biological safety
    - Radiation safety
    - Electromagnetic safety
    - Performance
    - Physicochemical characteristic
    - Stability
5. Background information on research and development, science
6. Clinical trial data
7. Uses in foreign countries

Items 5 through 7 are not required if the subject device is fundamentally equivalent to its predicate device. If the subject device is not equivalent to the predicate device, items 5 through 7 are required and the device requires the Clinical Data Review or CDR route.

Summary Technical Document (STED) formatting requirements

Class IV medical device applications must be submitted in Summary Technical Documentation (STED) format, and many elements should be provided in Korean. An e-copy of the original documents shall be attached in the STED submission file, with the summary and overview in Korean. The MFDS may require translation of the attachments. Table 10 of the Regulation for Approval, Notification, and Evaluation of Medical Device, MFDS Notification No. 2015-114 outlines STED requirements as listed below. As mentioned, STED format is not required for Class IV IVD submissions.

STED Requirements

Section 1: Application

Section 2: STED

1. Table of contents
2. Description and specification of the device
    a. General description of the device
    b. Reference document on similar device and predicate device
3. Draft of labelling
4. Design and manufacturing information
    a. Overview of device design
    b. Summary of manufacturing process
    c. Summary of location of design and manufacturing
5. Essential Principles Checklist
6. Summary of Risk Management
7. Verification and validation of the device
    a. General
        i. Declaration of Conformity on standards
        ii. Overview of device design validation
    b. Summary of electrical/mechanical safety test
    c. Summary of biocompatibility test
    d. Summary of radiation safety test
    e. Summary of electromagnetic safety test
    f. Summary of performance test
    g. Summary of software verification and validation data
    h. Summary of physicochemical characteristic data
    i. Summary of animal-derived material safety data
    j. Summary of stability test
    k. Summary of information on combined or compound drug
    l. Summary of animal test
    m. Summary of clinical trial data

Section 3: Attachments

1. Table of contents
2. Data on manufacturing process
3. Risk management report
4. Data on device verification and validation
5. Reference data

In-Country Testing

In general, the MFDS accepts foreign test reports that meet certain conditions. For manufacturers of active medical devices, the MFDS recognizes the IECEE CB Scheme. The MFDS also recognizes test reports that are accredited by the KOLAS (Korea Laboratory Accreditation Scheme). The KOLAS is the governmental accreditation body established by the Korean Agency of Technology and Standards (KATS). KOLAS is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA), which means that test reports from ILAC accredited testing labs will be accepted by the MFDS. However, the test report shall include a Korea deviation, which includes Korean standard voltage, frequency, and power plug specifications. Most manufacturers have to conduct additional testing to meet the Korean deviations.

MFDS also accepts biocompatibility test reports from overseas if such tests are from the Good Laboratory Practice (GLP) compliant testing labs located in one of the Organisation for Economic Co-operation and Development (OECD) countries.

While test reports are accepted by the MFDS under certain conditions, manufacturers should expect to conduct additional testing for Korea. Testing can be done where the manufacturer is based, if the lab is able to test to Korea specific standards; otherwise, manufacturers may send samples for testing at a lab in Korea. Common test requirements include performance and dimensional testing, among others. Patient-contacting devices usually require supplementary physical/chemical testing (USP 661), particularly plastic devices.

Novel devices or devices with a new indication will require Clinical Data Review by the MFDS. The MFDS maintains tables (Figure 3) for each device code where the necessity of clinical data and test requirements are identified based on several criteria. The comparison criteria are intended use, mode of action, raw material, performance, test standard, and instructions for use. Manufacturers must complete the table, comparing their subject device with a predicate device, to determine their application requirements.

Technical Document Requirements 제출자료 / Identifier 구분		1	2	3	4-Ga	4-Da	4-Ra	4-Ra	4-Ma	4-Ba	4-Sa	5	6	7
		Comparison Table of Predicate Device 본질적 동등품목 비교표	Intended Use Statement 사용목적	Mode of Action 작용원리	Electrical Safety Test 전기	Radiation Safety Test 방사선	EMC Test 전자파	Biocompat-ibility Test 생물학적	Performance Test 성능	Physio – chemical 물리화학	Stability 안정성	Clinical 임상	Origin or discovery/ grounds for development 기원·발견 및 개발경위	Foreign Uses 외국사용 현황
Novel Devices 새로운 제품	1. Differences in Intended Use 사용목적이 다른 것	O	O	X				O	O	O	O	O	O	O
	2. Difference in Mode of Action 작용원리가 다른 것	O	X	O				O	O	O	O	X	O	O
	3. Difference in Raw Material 원재료가 다른 것	O	X	X				O	O	O	O	Δ	O	O
Improved Devices 개량 제품	4. Difference in Performance 성능이 다른 것	O	X	X				X	O	X	X	X	X	X
	5. Difference in Test Standard 시험규격이 다른 것	O	X	X				O	X	X	X	X	X	X
	6. Difference in Usage Instructions 사용방법이 다른 것	O	X	X				X	X	X	X	Δ	O	O
Equivalent Devices 동등제품		O	X	X	X	X	X	X	X	X	X	X	X	X

Figure 3. Example of a submission checklist for a non-electrical device. O means item is required. X means item is exempted. Δ means case by case, so manufacturers have the opportunity to discuss the requirement with the MFDS. For this example, clinical data is required if there's a difference in intended use. Clinical data may be required if there's a difference in raw material and usage instructions, which means manufacturers can approach the MFDS for feedback if the differences do not warrant clinical data. Companies must provide information on their predicate device for MFDS review, which can be challenging to obtain for raw material. If the raw materials data cannot be provided, the company must submit clinical data.

The current regulations stipulate that clinical trial data from a human study is required for class III and IV devices to prove safety and efficacy; whereas clinical literature on predicate devices may be accepted for Class I and Class II devices. Data provided from a human study should meet one of the following requirements, at a minimum:

- Compiled from an MFDS approved clinical center – the MFDS publishes a full listing of approved clinical centers. Most of them are national or university hospitals
- Should be conducted to ICH Good Clinical Practices or ISO 14155 – the study must also include a sufficient Asian patient population
- Submitted for approval to an OECD country, such as the US, Canada, Japan, or the EU
- Published in a key medical society journal in the Science Citation Index (SCI)

Companies who are unsure if their clinical data will be accepted can ask the MFDS for feedback. This process is fairly straightforward and inexpensive, and provides manufacturers with an unofficial opinion from the MFDS. Companies who want a binding opinion can request a formal meeting, similar to the FDA's pre-sub process. However, pre-sub meetings are rarely requested, and incur additional costs and time.

Product registrations never expire. However, regulators will audit (KGMP) manufacturer facilities every three years. If there is a change to your manufacturing process, regulators will perform a desktop audit after the change.

Changes to the medical device should be analyzed to determine if a modification or technical documentation review is required. The MFDS published a list of minor change criteria, and manufacturers should check with their KLHs whenever changes are made to their devices. If a manufacturer fails to make the appropriate filing with the MFDS, auditors may issue a non-conformity during the KGMP renewal audit and require corrective and/or preventive actions to the manufacturer's CAPA system.

In addition, the MFDS actively monitors adverse events in other markets and takes appropriate steps in Korea. Manufacturers, KLHs, and distributors are required to report any adverse events to the regulatory authorities.

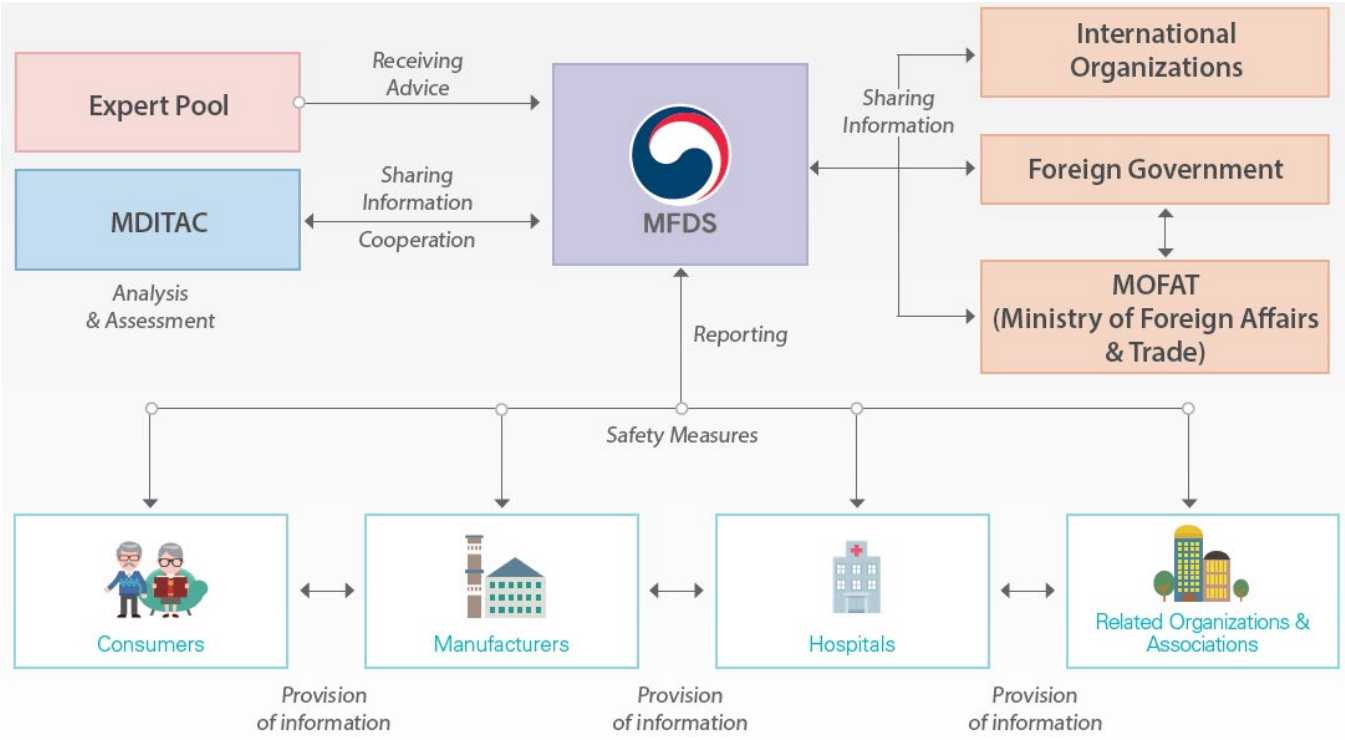


Figure 4: Adverse Event Reporting (Source: MFDS)

Conclusion

Although the Korean regulatory system may seem complex compared to other developed countries, it's a transparent system that is very manageable with the right help. Regulations and guidance documents change regularly, and manufacturers are strongly advised to partner with local experts to monitor any changes relevant to their operation in Korea.

Local distributors can be a useful resource to understand the system but will often not move forward unless they have exclusive marketing rights. Distributors may not understand the regulations to the level of RA/QA professionals. To stay abreast of compliance requirements, it's important to partner with an independent expert who monitors and understands the regulations.

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If you enjoyed this white paper, our South Korea device registration process chart might be useful to you. This chart illustrates the steps you must take to sell your medical device by classification, including representation, KGMP, testing, submission, review requirements, and more.

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