



Korean Medical Devices Regulations

The former Korea Food and Drug Administration (MFDS), an agency under MHW, regulating all Medical Devices was promoted to ministry level: Ministry of Food and Drug Safety (MFDS).

Structure of Korean legislation

- [Medical Devices Act \(MDA\)](#)
- [Enforcement Decree of MDA](#)
- [Enforcement Regulations of MDA](#) – framework of major regulatory programs and basis for GMP requirements in Annexes
- MFDS notifications of MDA – most detailed regulations for technical requirements, review standards and processes
 - Regulations for Reviewing Technical Document, etc. of Medical Device - Attached Table
- MFDS standards and guidelines – guidelines for industry and MFDS assessors

MFDS notifications related to Medical Devices

Under the legislations, most detailed regulations for technical requirements, review standards and processes are regulated as MFDS notifications. Some important notifications for device registration process are:

- Regulation on approval, notification and assessment of Medical Devices
- Standards for manufacture and quality management of Medical Device (GMP)
- Regulations for product classification of Medical Devices
- Re-evaluation (re-examination) of Medical Devices

MFDS standards and guidelines related to Medical Devices

MFDS standards are published upon demands from the industry and assessors, referring to widely recognized international standards, e.g. IEC and ISO standards, but considering national deviations. The standards are:

- Horizontal standards for electrical safety, biological safety, electro-compatibility and safety testing requirements
- Vertical standards for respective product categories

Guidelines as nonbinding documents are published for industry and MFDS assessors. Examples are:

- Guideline on Medical Device evaluation
- Guidelines on technical document review
- Guideline on labeling for Medical Devices
- Guideline on GMP audit
- Guideline on GMP audit for foreign manufacturers of imported products

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Classification of Medical Devices (MD) and responsible organizations

Class*	Criteria	Product assessment**		Product approval
		TDR	SER	
IV	Medical Devices with high risk	MFDS	MFDS	MFDS, Head Office
III	Medical Devices with medium serious potential risk			
II	Medical Devices with low potential risk	3 rd Party TF Reviewer	MFDS	MFDS, District Office
I	Medical Devices with little potential risk	NA	NA	NA

* The classification of each Medical Device is listed in a MFDS notification.

** A technical document review is a "general" technical file review (TDR) for those products that are basically the same as an already approved product, whereas a "safety and efficacy" review (SER) is required for devices unlike those currently available on the market – falling under new structure, new performance, new intended use, and newly developed Medical Devices.

Importer

To access the Korean Medical Device market, the importer based in Korea is to be designated for foreign manufacturers, and has to be:

- a business license holder for Medical Device import,
- possibly a subsidiary of foreign manufacturer, an independent distributor, local manufacturer or other legal entity,
- an applicant for product registration process and
- responsible for post-market surveillance

Premarket requirements

For marketing Medical Devices, the following requirements are to be fulfilled:

- Product license
- Quality System regulation – KGMP audit and approval

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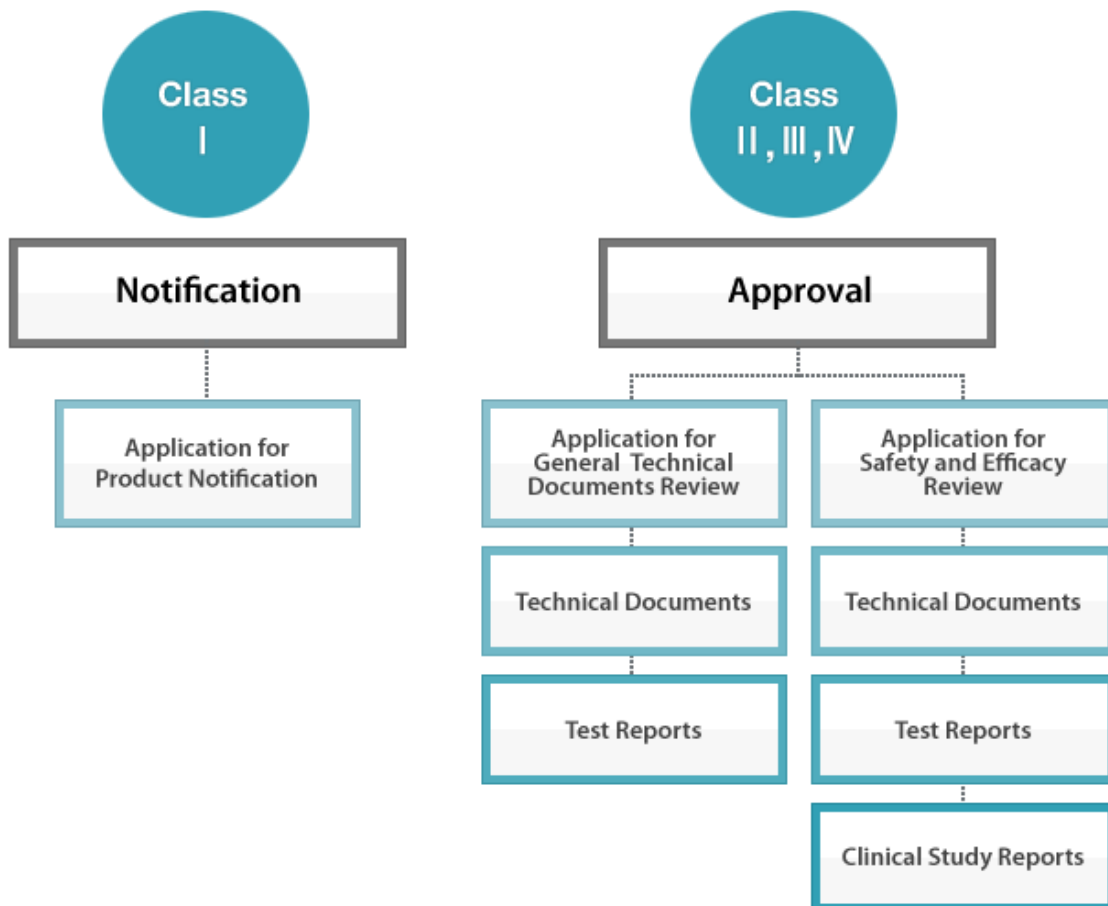


Product license

All Medical Devices require a premarket registration from MFDS before importing and putting into the market. There are two types of premarket product licenses:

- Premarket notification for class I devices
- Premarket approval for class II, III and IV devices

Premarket registration



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Premarket notification for class I devices

Premarket notification requires only a documentary review of product information.



Korea will not accept:

1. *Submission for a product requiring the approval process*
2. *Submission for a non-medical device*

Premarket approval for class II, III and IV devices

For class II Medical Devices the application must be submitted to MFDS, District Office, for product approval, after complete technical document review by 3rd party reviewers. A list of 3rd party reviewer organization for technical document review for ALL product categories of class II Medical Devices is available at the end of the present document. For class III and IV Medical Devices the application has to be submitted to MFDS, Head Office, for product approval after technical Document review by MFDS.

Option 1 : Package Application

Submit two sets of applications together : Technical Documents + Application for Product Approval

Option 2 : Sequential Application

- Submit an application for technical documents review first; after completing review of technical documents, submit an application for Manufacture/Import Product Approval

In case of class III and IV devices the applications for technical document review and for product approval can be submitted together. The application for certificate of product approval is a formal process by MFDS without any further technical review.

Technical document review

A technical document review is a general “technical document review” (TDR) for those products that are basically the same as an already approved product, whereas a “safety and efficacy review” (SER) is required for devices unlike those currently available on the market – falling under new structure, new performance, new intended use, and newly developed Medical Devices. Technical documents for all class II Medical Devices are reviewed by 3rd Parties, whereas class III and IV Medical Devices are reviewed by MFDS.

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General Technical Document Review (TDR)

- Devices substantially equivalent as previously approved products
- Clinical study reports are not required

Safety and Efficacy Review (SER)

- Required for devices with new-to-market features – new developments, new performance, new structure, and/or new intended use
- Significant difference affecting safety and effectiveness
- Clinical study reports are essential, in addition to TDR requirements

Technical Document file contains

- Intended use (IFU)
- Physical, chemical characteristics
- Biological safety
- Electromagnetic compatibility
- Stability report (shelf-life test)
- Principle of operation
- Electrical, mechanical safety
- Irradiation safety
- Function

In addition to TDR, SER requires:

- Original developer
- Clinical investigation data
- Design history and background
- Market history in foreign countries

In the product registration procedure, the class II Medical Devices defined as “equivalency-notified products” are exempt from technical document review process, and those defined as “modified products” are partially exempt.

What is a “equivalency-notified product”?

- Medical Devices, which are equivalent to premarketed devices for the intended use, operation principle or used materials (for non-active Medical Devices), performance, test specification and operation method, etc.
- Equivalency-notified and regularly updated by MFDS
- Test report required to identify the “equivalency” issued
- by MFDS-registered test laboratories

Medical Device testing

The test reports issued by the following laboratories are recognized to support the function, safety and effectiveness

- MFDS-registered laboratories
- IEC-registered laboratories (CBTL)
- KOLAS-accredited laboratories (Korea Laboratory Accreditation Scheme acc. to ISO 17025)
- GLP laboratories accredited according to OECD rules

3rd Party organizations can provide IEC reports and GLP reports for MFDS registration.

Clinical trials

- Required for SER - products
- MFDS approval required for protocol and clinical trial studies
- Clinical investigation by Medical Device clinical trial centers qualified by MFDS (GCP)

The clinical studies performed in foreign countries are recognized only if:

- Compliance to GCP and ISO 14155

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- The study reports have been accepted by the health competent authority of OECD member countries in the product registration process

Quality system regulations (KGMP)

All Medical Devices are required to be manufactured under GMP. Premarket GMP audit is mandatory for all class II, III and IV devices and class I (sterile and measuring devices).

- Certification of compliance to “Standards for manufacturing and quality management of Medical Devices“ (KGMP, similar to ISO 13485)
- Both document review and site inspection conducted by 3rd party GMP inspector organization, the audit team accompanied by MFDS officer if necessary
- Update every 3 years

Currently, a MFDS guideline was published on “GMP audit for foreign manufacturers of imported products” and implemented with the time frame:

- Class IV: from April 8, 2012
- Class III: from 2013
- Class II/I (sterile and measuring): from 2014

In case of many manufacturing sites per importer, the manufacturing sites will be sampled per depending on the criteria of product risk, importing volume, PMS data, etc.

The following issues are not focused during TDR/SER process but during the GMP-audit:

- Sterilization process validation
- Risk management file

Class	Initial	Follow-up	Renewal	Additional ⁴
I	None ¹	None ¹	None ¹	None
II	3 rd Party Audit ²	Documentary Review ¹	Documentary Review ³	Documentary Review
III	Joint Audit ²	Documentary Review ¹	Documentary Review ³	3 rd Party Audit ⁵
				Joint Audit ⁶
IV	Joint Audit ²	Documentary Review ¹	Documentary Review ³	Joint Audit

1_J Document Review removed after September 16, 2013

2_J Can be replaced by documentation review if domestic importers have valid approval certificate for the manufacturer. Yet, Manufacturers that have had KGMP non-compliance issues within three years or that have reported any safety or efficacy problems prior to an inspection will also undergo inspections.

3_J Class 2,3,4 medical devices inspection may be executed through document review. Still, Manufacturers that have had KGMP non-compliance issues within three years or that have reported any safety or efficacy problems prior to an inspection will also undergo inspections (class 1, 2 : subject to a 3rd party audit, class 3, 4 : subject to a joint audit).

4_J importers representing several foreign manufacturers must have only one of those manufacturers undergo onsite audits (documentation review applies to the other manufacturers).

5_J Manufacturers that have had no KGMP non-compliance issues within three years or that have not reported any safety or efficacy problems prior to an inspection will also undergo inspections by third-party auditors, who will then report findings to the MFDS for final decision

6_J Any KGMP non-compliance issues in the previous three years will require a joint third-party and MFDS audit. Any safety and/or efficacy issues reported will also require a joint MFDS/third-party audit of a manufacturing site

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Postmarket surveillance

The product license holder (local manufacturer and importer) has legal responsibility for the product marketing process and postmarket surveillance activities:

- Patient record control required for designated products for Medical Device tracking such as cardiac implant devices, breast implants, implantable infusion devices, defibrillator and continuous ventilator
- Adverse event/safety alert reporting for adverse effect, new safety information from PMCF and/or literature
- Recalls in case of effects on safety, effectiveness or quality defects
- Re-evaluation and re-examination

Approved 3rd Party organizations:

Korea Testing Laboratory
Korea Testing and Research Institute
Korea Testing Certification
Korea Conformity Laboratories
TUV SUD Korea
SGS Korea

How Kobridge can help for the South Korean market:

- Technical document preparation before review by MFDS or 3rd Party
- South Korea MFDS mock inspection service
- Medical distributor search and evaluation in Korea
- Act as the License holder or importer
- South Korea MFDS Medical device registration and approval
- Korean KGMP quality management compliance
- Follow-up post-market activities

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