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for the medical device industry

Introduction to Korean medical device regulations

The Ministry of Food and Drug Safety (MFDS) is the healthcare agency having overall responsibility for medical devices in Korea.

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*
- 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 devices (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

* The regulations with most current versions are to be checked via the MFDS website (www.mfds.go.kr). The laws and notifications are partly available in English, but not always as latest versions.

Classification of medical devices (MD) and responsible organizations

Class*	Criteria	Product assessment**		Product approval	GMP audit
		TDR	SER		
IV	Medical devices with high risk	MFDS	MFDS	MFDS, Head Office	Third-party GMP inspector + MFDS officer
III	Medical devices with medium serious potential risk				
II	Medical devices with low potential risk	Third-party TF reviewer	MFDS	MDITAC***	
I	Medical devices with little potential risk	–		MDITAC***	n/a

* 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.

*** Medical Device Information & Technology Assistance Center

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 a foreign manufacturer, an independent distributor, local manufacturer or other legal entity,
- an applicant for product registration process and
- responsible for postmarket surveillance.

Premarket requirements

For marketing medical devices, the following requirements are to be fulfilled:

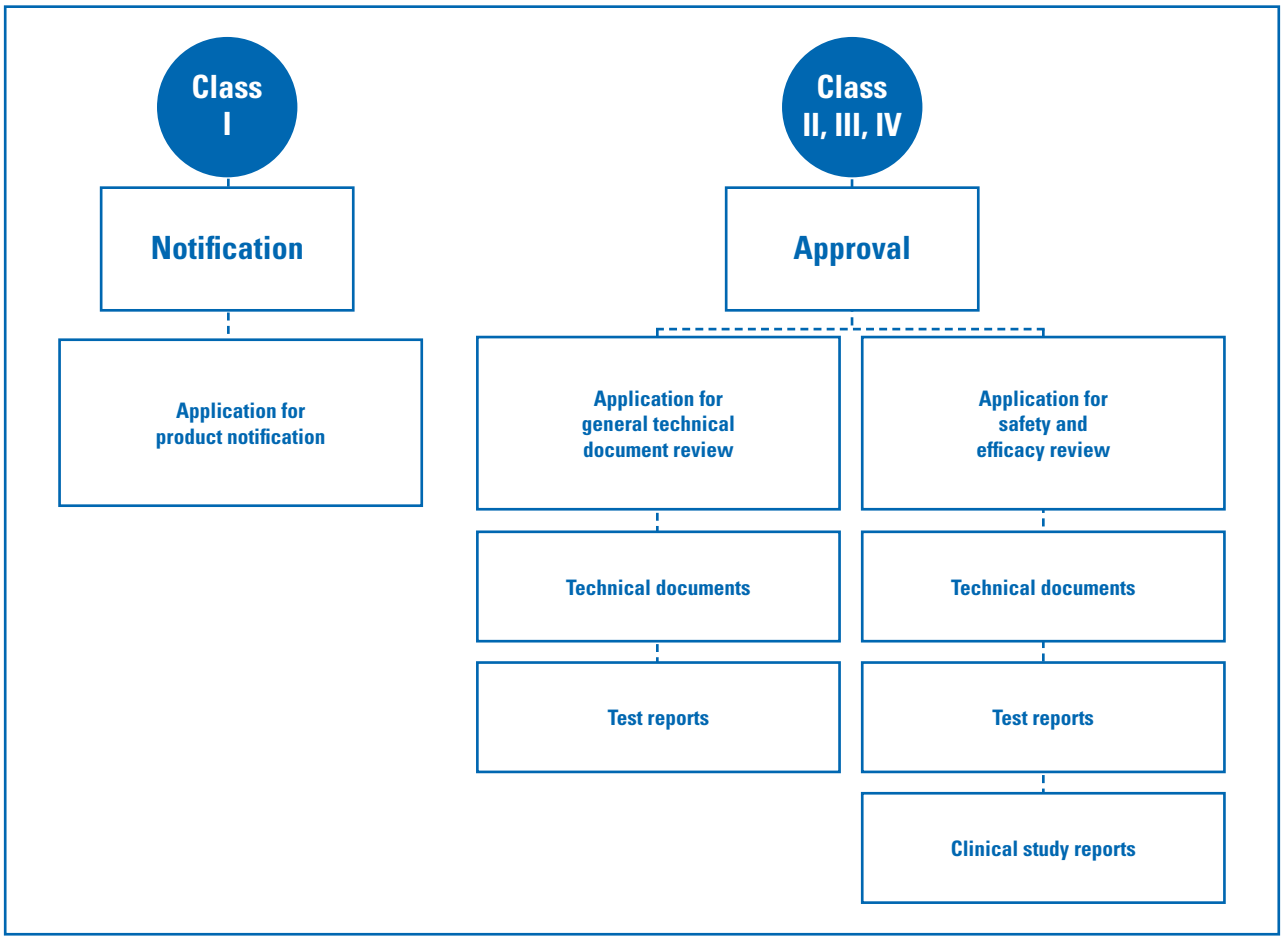
- Product license
- Quality system regulation – KGMP audit and approval

Product license

All medical devices require a premarket registration from MFDS before importing and putting on the market. There are two types of premarket product licenses:

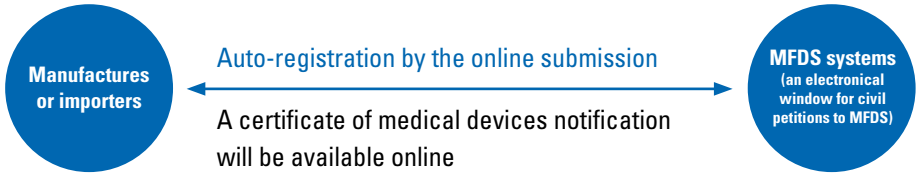
- Premarket notification for Class I devices
- Premarket approval for Class II, III and IV devices

Premarket registration



Premarket notification for Class I devices

Premarket notification requires only a documentary review of product information.



MFDS does not accept:

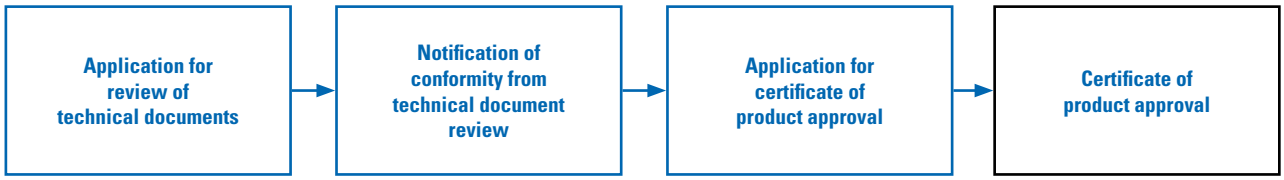
- Submission for a medical device requiring the approval process
- Submission for a nonmedical device

Premarket approval for Class II, III and IV devices

For Class II medical devices the application must be submitted to MDITAC for product approval, after complete technical document review by third-party reviewers.

TÜV SÜD Korea is a third-party reviewer organization for technical document review for **all** product categories of Class II medical devices.

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.



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 third parties, whereas Class III and IV medical devices are reviewed by MFDS.

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 (including 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 the 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 nonactive medical devices), performance, test specification and operation method, etc.
- Additional information has to be given for the device under review
- 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

TÜV SÜD 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
- 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 third-party GMP inspector organization, the audit team accompanied by MFDS officer
- 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 from 2014

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

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

- Sterilization process validation
- Risk management file

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

Our service for medical device registration

- Technical document review service for **all** Class II medical devices as third-party reviewer, registered to MFDS
- CB report issuance for electrical/electronic medical devices
- GLP report issuance for biocompatibility of body-contact medical devices
- Pretechnical meeting to identify the gaps for MFDS approval
- KGMP mock inspection service

Your contact partner at TÜV SÜD Product Service can provide further information.

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