# Overview and Update of Medical Device Regulations in Korea

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MINISTRY OF
FOOD AND DRUG SAFETY

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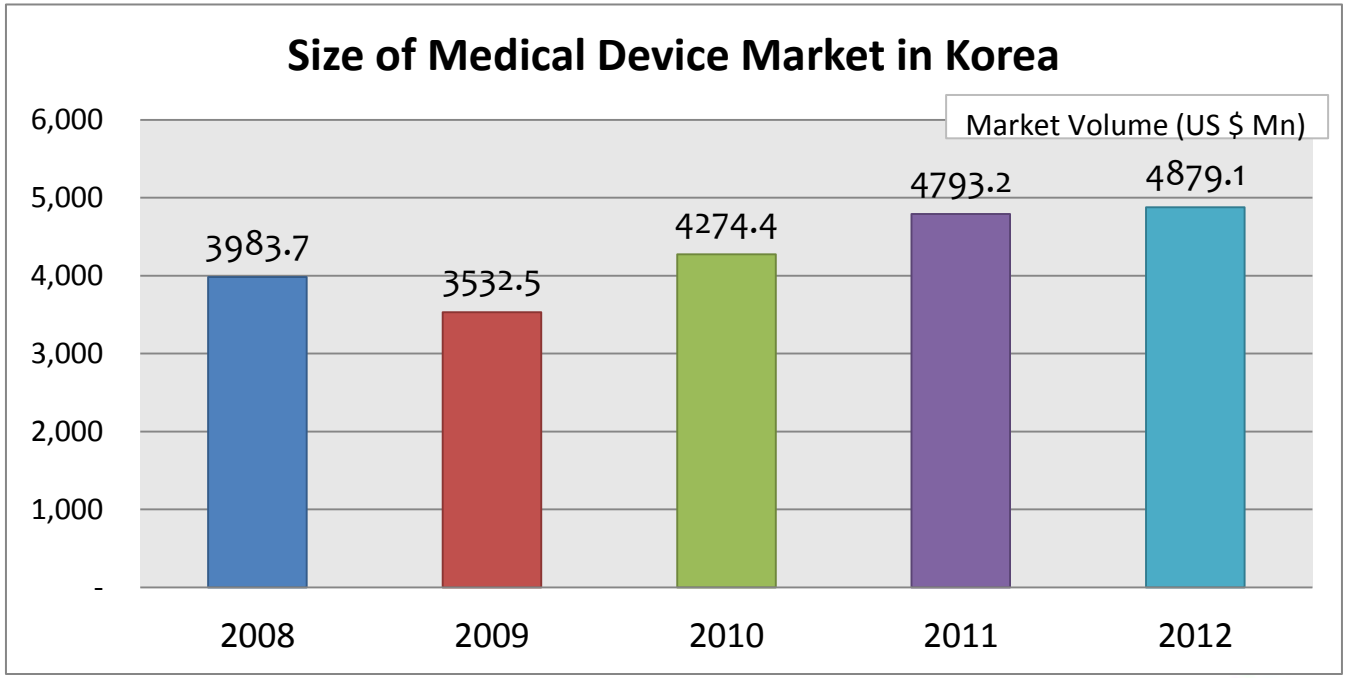
# I. Status of Medical Device Industry in Korea

# Medical Device Market in Korea

(US $ Mn)

| 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|
| 3,989 | 3,533 | 4,274 | 4,793 | 4,879 |

CAGR 5.2%




The World Medical Markets Fact Book 2013, Espicom

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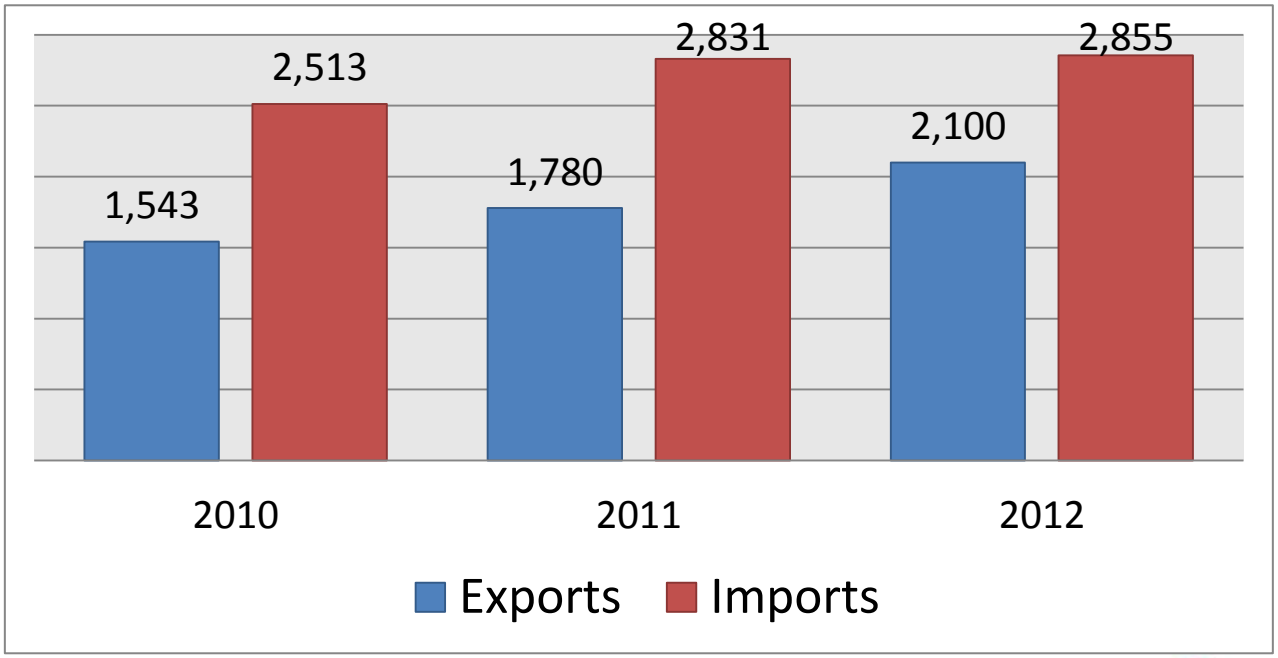
# Medical Device Market in Korea

(USD MN)

| | 2010 | 2011 | 2012 |
|---|---|---|---|
| **Exports** | 1,543 | 1,780 | 2,100 |
| **Imports** | 2,513 | 2,831 | 2,855 |




The World Medical Markets Fact Book 2013, Espicom

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# Korea's Top 10 products in 2012

| | Production | Export | Import |
|---|---|---|---|
| **1** | Ultra sound imaging diagnostic device | Ultra sound imaging diagnostic device | Coronary Vascular Stents |
| **2** | Dental implants | Soft contact lenses | Soft contact lenses |
| **3** | Dental alloy | Dental implants | MRI system |
| **4** | Sight corrective ophthalmiclens | Sight corrective ophthalmiclens | CT system |
| **5** | Medical image processing device | IVD strip for Glucose analyzer | Internal Knee prosthesis |
| **6** | Electric heating pad system for home use | Electric heating pad system for home use | Disposable dialyzer |
| **7** | Digital X-ray diagnostic system | Probe for clinical use | Sight corrective ophthalmiclens |
| **8** | Soft contact lenses | Digital imaging processing device· so ftware | Probe for clinical use |
| **9** | Probe for clinical use | Digital X-ray diagnostic system | Intravascular catheter |
| **10** | Combinational stimulator for home use | Combinational stimulator for home use | Ultra sound imaging diagnostic device |

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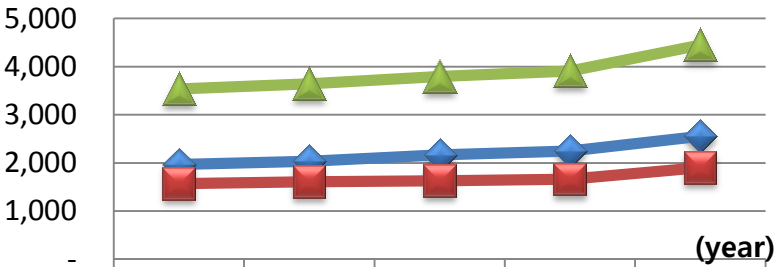
# Top 20 Manufactures in Korea

(in production value)

| No | Company Name | No | Company Name |
|---|---|---|---|
| 1 | Samsung Medison | 11 | Daemyung Optical |
| 2 | Osstem Implant | 12 | NeoBiotech |
| 3 | GE Ultrasound Korea | 13 | Dentium |
| 4 | NUGA Medical | 14 | Heesung Catalysts. |
| 5 | Vatech Networks | 15 | Corentec |
| 6 | Simens Ultrasound EHS Engineering(Pohang) | 16 | Nanoomtech |
| 7 | Ceragem | 17 | DIO |
| 8 | Simens Ultrasound EHS Engineering | 18 | Viewworks |
| 9 | Shinhung | 19 | GEMSS Medical Systems |
| 10 | ACE Medical | 20 | Daemyung Optical |

# Medical Device Business Entities

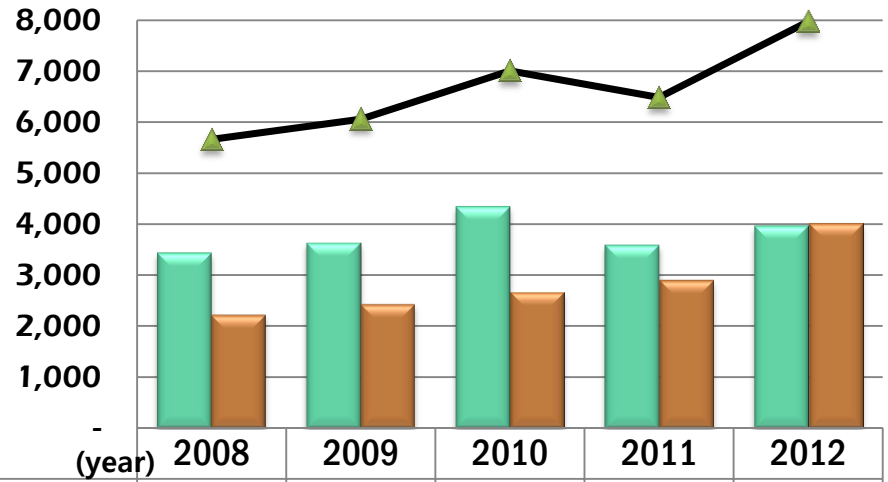
## Number of device business entities




| | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|
| Manufacturer | 1,964 | 2,031 | 2,168 | 2,245 | 2,550 |
| Importer | 1,571 | 1,609 | 1,626 | 1,662 | 1,898 |
| Total | 3,535 | 3,640 | 3,794 | 3,907 | 4,448 |

## Product Approval

No. of product approval and notification




| | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|
| Notification | 3,437 | 3,631 | 4,341 | 3,585 | 3,959 |
| Approval | 2,224 | 2,429 | 2,666 | 2,899 | 4,013 |
| Total | 5,661 | 6,060 | 7,007 | 6,484 | 7,972 |

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# II. MFDS Organization and Responsibilities

# Ministry of Food and Drug Safety (MFDS)
## [former KFDA]

**March 23, 2013 KFDA was promoted to**
**the Ministry of Food and Drug Safety(MFDS)**
**as a administration restructuring measure by the President Park Geun-Hye.**

**Headquartered in O-Song**
**http://www.mfds.go.kr**



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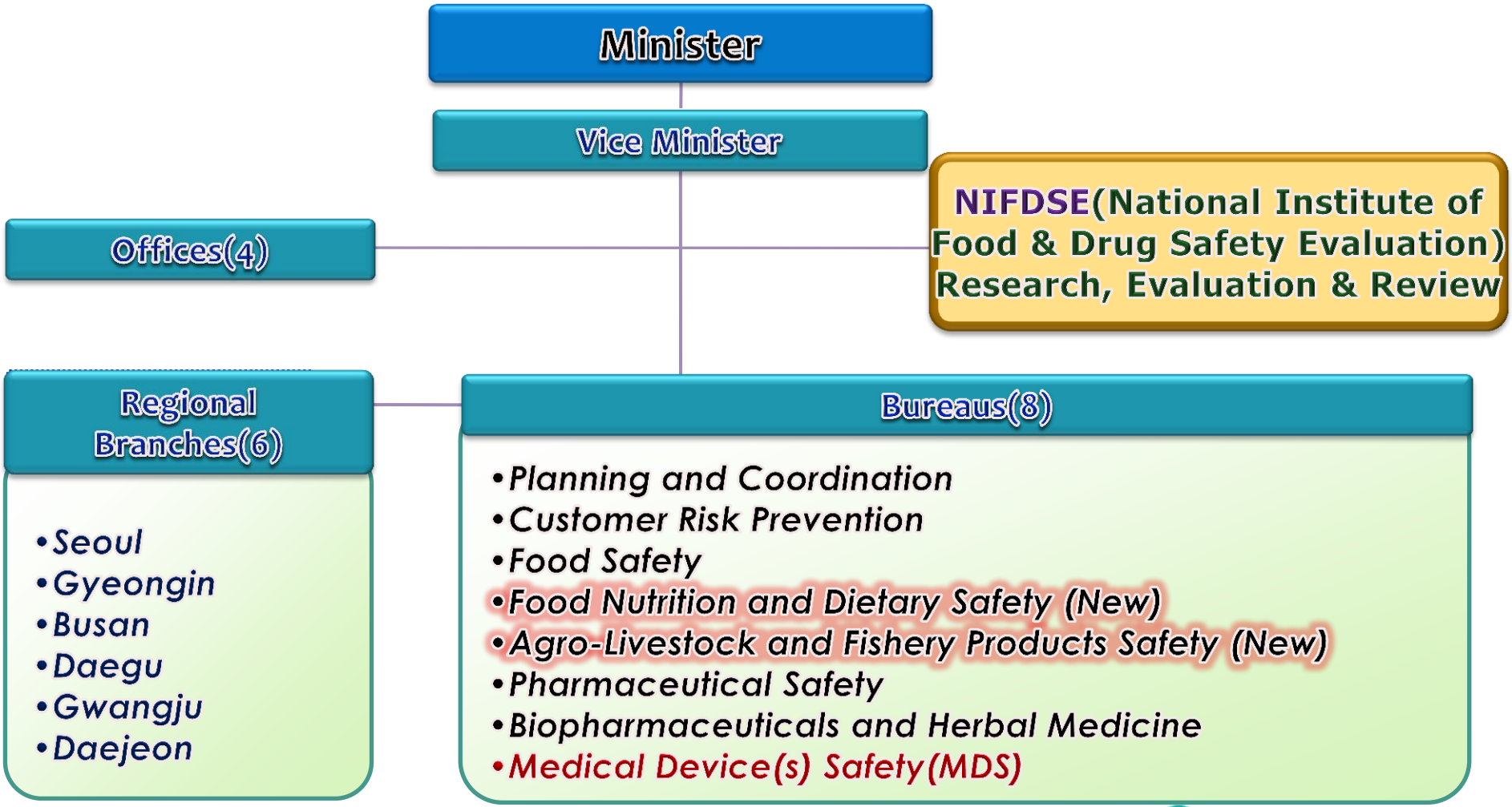
# Organization of MFDS




**Total : 1,760** persons

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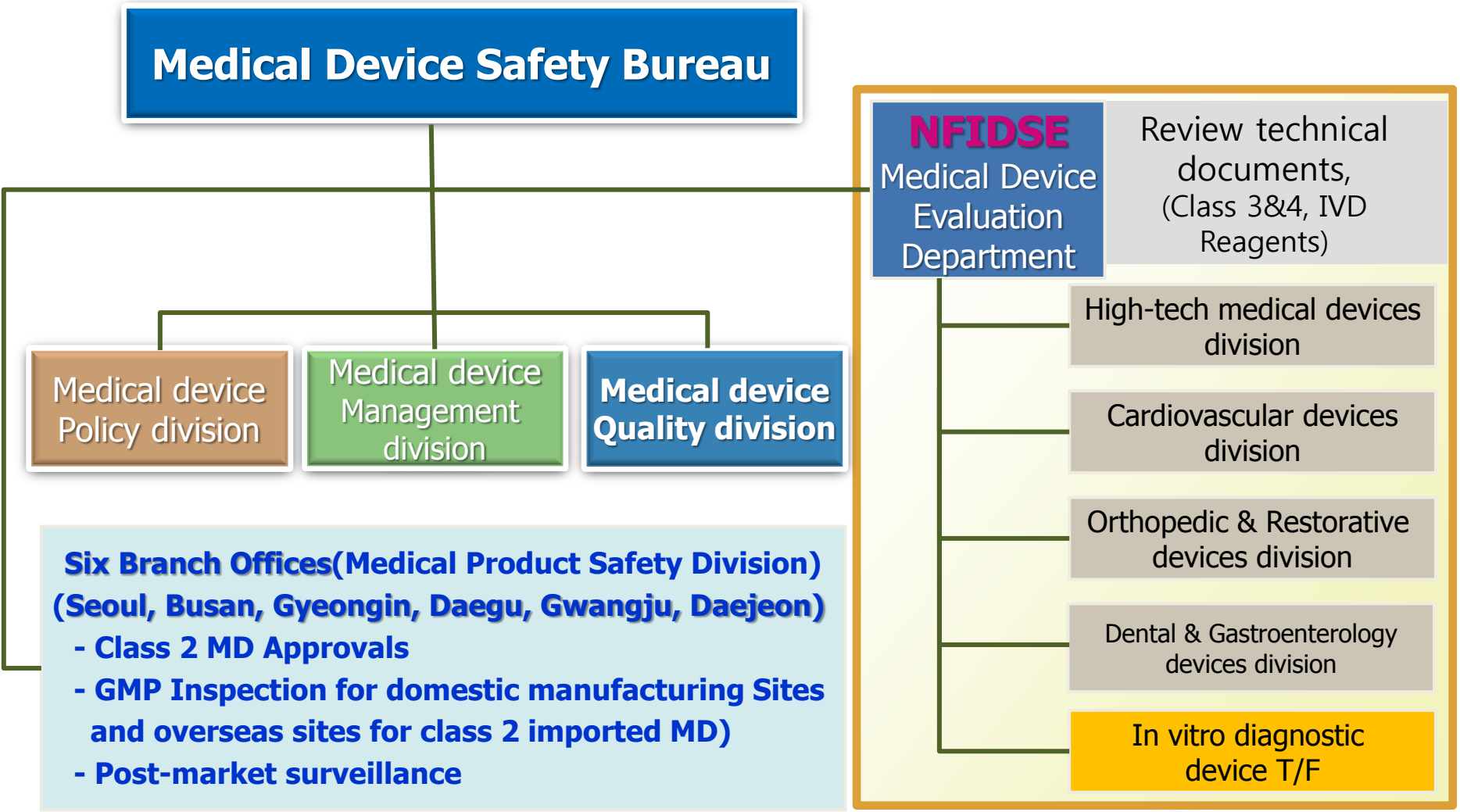
# Organization of MDS Bureau

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# Other Related Organizations

## Subsidiary Organization

| | |
|---|---|
| Medical Device Information & Technology Assistance Center (MDITAC) | Legal entity established by Medical Device Act<br>Supports and provide information regarding clinical investigations, standards, safety, training, etc.<br>(established June , 2012) |

## Collaborating Third-party Organization

| | |
|---|---|
| Medical device Testing Laboratories | Test labs for medical devices (13 labs) |
| Medical device QMS Audit Institutions | Quality Management System(GMP) audit & issue certificate with MFDS (4 Institutes) |
| Technical Document Review Agency | Review of Technical Documents on Class 2 devices (6 Institutes) |
| Medical device Clinical Trial Centers | Hospitals accredited by MFDS for Medical device clinical trials (total 128) |
| Korea Medical Device Industry Association | Industry association approved by MFDS<br>Advertisement review, Performance reports, Customs prediction report, Representatives of Medical Device Industry |

# III. Medical Device Regulation Overview

# Medical Device Regulations

## MISSION

- To protect and promote public health by assuring the public access to **safe, effective, and high-quality medical devices**

## OUTLINE

- **Risk-based** regulations (4 Classification system)
- Regulations through **life-span of a medical device**
- **Internationally harmonized** regulations
- Facilitate **medical device innovation** by advancing regulations
- Enhance predictability, consistency, transparency, and efficiency

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# History of Medical Device Regulations

| | |
|---|---|
| 1953 | • **Pharmaceutical Affairs Act** provides the definition of medical devices<br>• Introduce a regulatory system for licensing manufacturing business and product approval |
| 1965 | • Introduce the requirements for production control and reporting |
| 1996 | **KFDA Established** |
| 1997 | • Introduce the classification system of medical devices based on risk level(3 classes)<br>• Implement regulations for good manufacturing practices<br>• Introduce two different pre-market pathways: (1) notification; and (2) approval<br>• Eliminate local testing requirements for each and every shipments of imported medical devices |
| 2004 | • **Legislate Medical Device Act**<br>• Changed to a four-class system<br>• Begin regulating device import business, refurbishing business and rental business<br>• Strengthen post-market surveillance system |
| 2007 | • Implement a full-scale KGMP/GIP regulations |
| 2012 | • Establishment of the Medical Device Informaton & Technology Assistance Center |
| 2013 | **KFDA reorganized as MFDS** |

# Classification of Medical Devices

➔ **Risk Based regulation : Classification of medical devices**

4 classes based on potential risk to human health and purpose of use

Harmonized with GHTF/IMDRF rules

2,202 items are designated by current Ministerial Notification

| Class | Risk levels & Purpose of Use | Device Examples | Numbers of classified devices |
|---|---|---|---|
| I | Little Risk | Forceps for medical use, Mechanical Stethoscope | 601 |
| II | Low Risk | Syringe, Infusion pump | 1,008 |
| III | Moderate Risk | Silk Suture, Contact lens | 339 |
| IV | High Risk | Coronary stent, Intracardiac patch | 252 |
| I~IV | | | 2 |
| **Total** | | | **2,202** |

# Overview of Medical Device Regulations

| Flowchart | | | Regulatory System | | |
|---|---|---|---|---|---|
| | | | Relevant Tasks | | Regulatory Body |
| Pre Market | Business License | | ▪ Manufacturing · Importing License (25 days) | | Regional MFDS Offices |
| | Device Product Notification, Approval | Notification (Class Ⅰ) | ▪ Notification & Registration of Class Ⅰ (distributable immediately at Registration) | | Regional MFDS Offices |
| | | Approval (Class Ⅱ~Ⅳ) | ▪ Approval of Clinical Trials Plan (30days) (if needed) | | MFDS |
| | | | ▪ Review of TD (55~70days) | Class Ⅱ | the Third party |
| | | | | Class Ⅲ · Ⅳ | NIFDS (Evaluation dept.) |
| | | | ▪ Approval (10 days) | Class Ⅱ | Regional MFDS Offices |
| | | | | Class Ⅲ · Ⅳ | MFDS |
| | QMS Inspection | | ▪ Inspection (37days) | Class Ⅱ~Ⅳ (manufactured devices), Ⅱ (imported devices) | Regional MFDS Offices /the Third party |
| | | | | Class Ⅲ·Ⅳ (imported devices) | MFDS/ the Third party |
| Sales | Business License | | ▪ Distribution, Rental (3days), Repairing Business(20days) | | Competent local government |
| Post Market | Post - Market Surveillance | | ▪ QMS inspection (every 3 years) | | MFDS or Regional Offices /the Third party |
| | | | ▪ Essential Compliance Requirements for Manufacturer, Importer, Distributor, Repairer, Renter | | MFDS/Regional Offices/ Competent local government |
| | | | ▪ Re-examination, Re-evaluation<br>▪ Labeling and Advertisements<br>▪ Prohibition of Activities in General | | MFDS<br>Regional MFDS Offices |
| | | | ▪ Tracking and Control<br>▪ Record Keeping<br>▪ Adverse Event Report | | MFDS<br>Regional MFDS Offices |
| | | | ▪ Report and Inspection<br>▪ Recall, Removal, Orders to Suspended Use<br>▪ Revocation of license and Business Suspension | | MFDS<br>Regional MFDS Offices |
| Customs Clearance | | | ▪ Standard Customs Clearance Report (1day) | | KMDIA |

# Approval of Class II·III·IV Medical Devices

## - CLASS II -

Application

Regional Offices

TD Review Institution

Clinical Study Plan Approval (If applied)

| Products with recognized SE | SE Products | Modified Products | New Products |
|---|---|---|---|
| Test Report | Test Report, Comparison data | Test Report, Comparison data Origin & development process , Usage Status Overseas (Clinical Data) | Test Report, Comparison data, Mode of Action, Safety & Performance data, Origin & Development Process, Clinical Data, Usage Status Overseas |

## - CLASS III & IV -

Headquarter

Application

| Class III & IV Products | Clinical Study Plan Approval (If applied) |
|---|---|
| Test Report, Comparison data, Mode of Action, Safety & Performance data, Origin & Development Process, Clinical Data, Usage Status Overseas | |

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# IV. Regulation Updates

# Approval & QMS Inspection Process

## Background

<Current> QMS Certification before distribution

① Product Approval Application → product approval → Application for QMS conformity → Conformity → Distribution

OR

② Product Approval Application + QMS Conformity Assessment Application → Conformity → Distribution

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# Approval & QMS Inspection Process

## Amended

QMS Certification before approval

Approval Application
Includes
QMS Conformity
Assessment Application


Distribution

## Effective

- as of six months after the promulgation of the MDA Amendment

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# Submission of Clinical Investigation data

## Background

- To Clarify MD which require to submit Clinical Investigation Data

## Amendment

- MD designated by the Minister : Clinical Investigation data is required
  - Minister designates the list of MD for Clinical Data submission
  - The list developed by the Working Group composed of the Industry, Academia, the 3rd Review party and MFDS

## Effective

- as of one year after the promulgation of the MDA Amendment

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# The IVD reagent Regulatory System

## Background

- IVD regulated medical devices and pharmaceuticals
  - IVDD : a medical device
  - Reagents : medical devices or pharmaceutical products

※Some of IVD reagents belong to pharmaceuticals

## Amendment

- All IVD reagents to be regulated as medical devices

## Effective

- As of Six months after the promulgation of the MDA Amendment

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# Strengthening the Good Supply Practice

## Background

- To enhance safety and quality control after distribution
- Obligation to comply with the Quality maintenance, sales order and etc.

## Amendment

- Compliance with **GSP of medical devices**
  - Detailed requirements for facilities and equipments of distributors
  - Appointment of a personnel responsible for GSP
  - Quality Management and environment sanitary control
  - Document and records keeping
  - own training programs for workers

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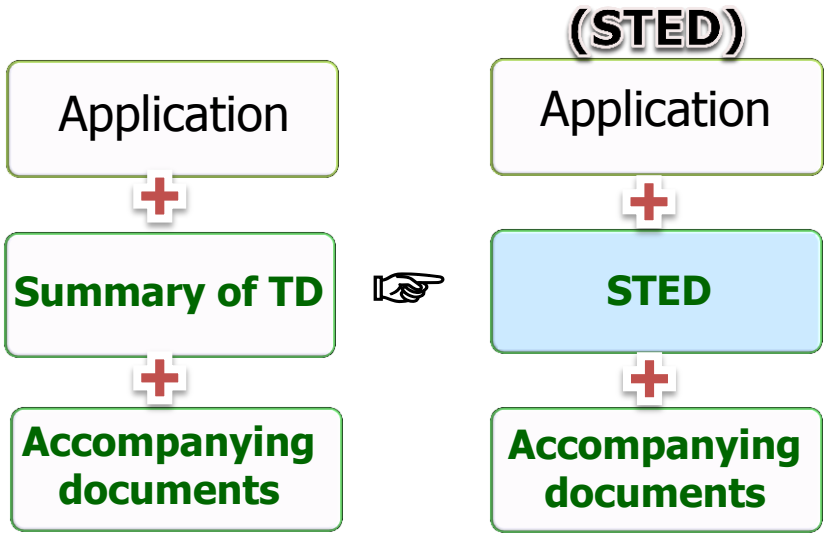
# International harmonization on STED

**STED are required for Class 4 (except IVD reagent)**

**- enforced as of 2014. Jan. 1**

**- optional for other Classes**




❖ **STED : Summary Technical Documentation for demonstrating conformity to the safety and performance of medical devices**
**: proposed by GHTF(IMDRF) including design verification, risk analysis & manufacturing process regarding safety and performance**

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# Streamline regulatory process for lower-class devices or devices of established safety

- **QMS inspection exemption for class I devices**

- **Expanding the Minor Changes exempted from pre-approvals**
  Minor Changes to approved Medical Devices or insignificant changes from approval application which do not impact its safety & performance
  ⇨ do not require approval process ⇨ report the changes to MFDS through the MFDS on-line system

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# Streamlining MD Classification Procedures

## Background

- MD Designation and Classification regulated by a Ministerial Notification
- New medical devices call for Notification Revision

※ Due to a long series of amendment process and frequent updates , prompt revision is difficult

## Amendment

| current | amended |
| --- | --- |
| - Category: Notification (e.g. Medical Instrument)<br>- Middle-category: Notification (e.g. Anesthesia apparatus)<br>- Specific category: Notification (e.g. Intravenous Anesthesia system) | - Category : Notification<br>- Middle category : Notification<br>- Specific category : Public announcement |

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# Reinforce Outside Experts Participatory Review

## Outside experts participatory review

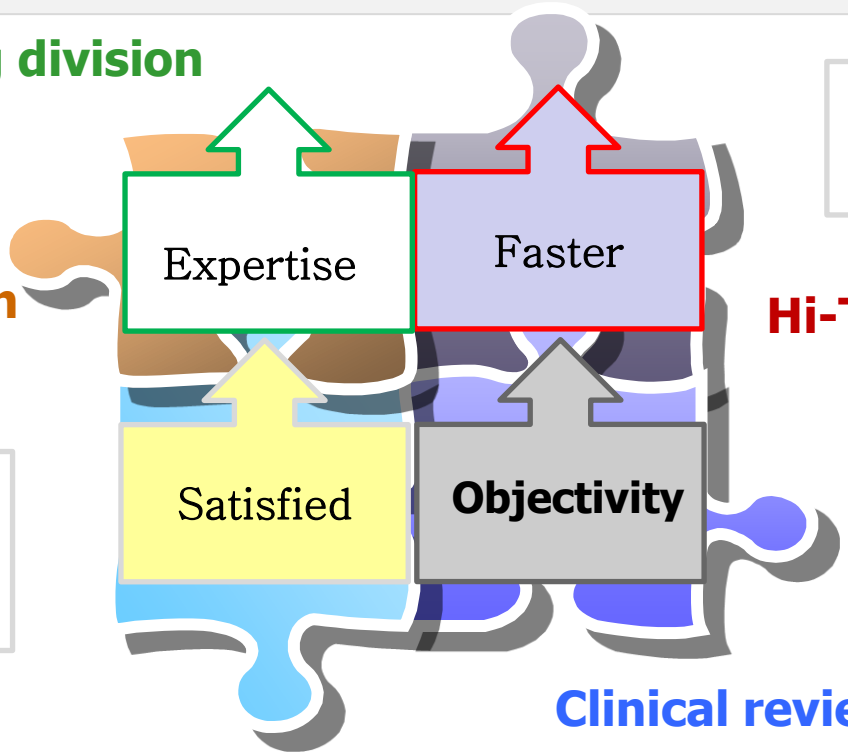
Outside experts participating in consultation & review for hi-tech and newly developed medical devices
- experts from each areas including medical specialists

**R & D consulting division**

**Analysis on R&D trend**

**Int'l cooperation division**

**Int'l cooperation & research on foreign regulations**




**Data on int'l standards, trial specifications animal tests**

**Hi-Tech review division**

**Supporting clinical study plan & examining guidance**

**Clinical review division**

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# Thank you for your attention!

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