



IMDRF International Medical Device
Regulators Forum

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Regulatory Update on Medical Devices in the Republic of Korea

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HSA
Health Sciences Authority



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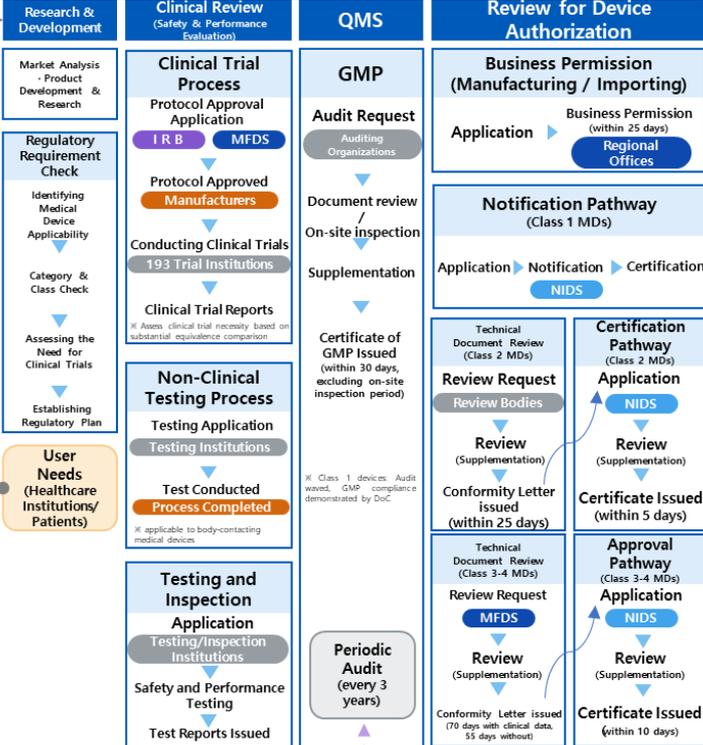
- ❖ Korean Medical Devices Regulatory Framework
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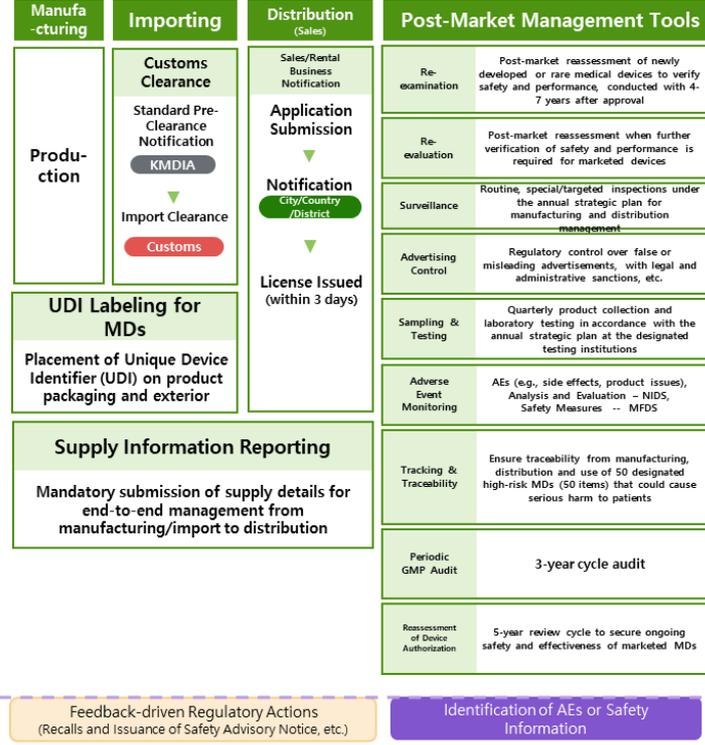
Medical Devices Regulatory Framework

Medical Devices Lifecycle Safety Management

Pre-Market Phase



Post-Market Phase



Support for MD Industry Development, Designation of Innovative MDs, Regulatory Assistance for Approval of Newly Developed MDs, and Provision of Standard Reference Materials for IVDs, etc.

Approval Pathway
Emergency Use Designated MDs for rare diseases or urgent introduction, and Export Requirement Exemptions (Test-use devices, etc.)
Use Authorization (Approval Exemption),
Approval Pathway



■ Medical Devices Act – Key Update

1. Priority GMP Audit System Introduced (Effective: Dec. 9, 2025)

AS-IS (Before revision)

- All GMP applications processed in the same order
- Reviewed through a single standard audit pathway



TO-BE (After revision)

- Priority audit pathway introduced
- Ensures stable supply and supports rapid market entry

❖ Public Health-Driven GMP Audit Prioritization

- Shift from uniform chronological processing
- To urgency- and impact-based prioritization
- To ensure stable supply and timely market entry

❖ Medical Devices Eligible for **Priority GMP Audit**

- ✓ Medical Devices Subject to Production/Import Suspension Reporting
- ✓ Newly Developed Medical Devices
- ✓ Innovative Medical Devices
- ✓ Medical Devices designed to provide information in braille or audio for persons with visual or hearing impairments



■ Medical Devices Act – Key Update

2. Long-term Tracking of Implantable Medical Devices

❖ **Legal Framework Established** (Effective: Jan 31, 2025)

- To enable patient-based data collection and evaluation through voluntary registration, including:
 - Product information
 - Procedure-related data
 - Adverse event information

❖ **Subordinate Regulations Amended** (Effective: Aug 1, 2025)

- To implement regulations on Real-World Data (RWD) utilization
 - Legal grounds for processing sensitive information
 - Defined scope of designated implantable devices



■ Medical Devices Act – Key Update

3. Enhancing Oversight of Third-Party Auditors and Audit Organizations

❖ Strengthening Governance and Accountability in the Third-Party Audit System

- Establishing clearer regulatory controls for third-party auditors and audit organizations (including QMS audit bodies), through:
 - Legal basis for appointment and revocation of manufacturing and QMS auditors
 - Legal basis for designation of auditor training institutions
 - **Four-year designation validity** period introduced for:
 - Technical documentation review bodies
 - Delegated conformity assessment bodies
- Renewal required prior to expiration to ensure continued competence



■ Act on Nurturing of MDs Industry & Supporting Innovative MDs – Key Update

❖ Promoting Innovation through Regulatory Support

- Dedicated authorization pathways for **designated innovative medical devices**
 - Priority and stepwise review mechanisms applied
- Aimed at accelerating access to breakthrough technologies
 - Supporting timely market entry and enhanced patient access
 - ✓ 133 devices designated (as of 2025)
 - 45 AI/big data-based products designated in 2025
 - ✓ Number of products designated by year

Year	2020	2021	2022	2023	2024	2025	Total
No.	8	9	11	31	29	45	133



Generative AI for chest disease diagnostic support



■ Digital Medical Devices Act – Key Update

1. Digital Healthcare & Health Support Device System (Effective: January 2026)

❖ What are Digital healthcare & health support devices?

- MFDS-designated mobile apps, smart devices, and similar products
- Not regulated as medical devices
- Intended to:
 - ✓ Support medical care
 - ✓ Promote health maintenance & improvement

AS-IS

- Heart rate
- Oxygen saturation
- Body composition indicators
- Step count



TO-BE (Scope Expansion)

- Broader biometric indicators
- Exercise and diet management
- Mental health management, etc.



■ Digital Medical Devices Act – Key Update

1. Implementation of the Digital Healthcare & Health Support Device System (Effective: January 2026)

❖ Strengthened Distribution Oversight against False or Exaggerated Advertising

- Voluntary Reporting System

- Companies may voluntarily submit product information to MFDS
- Submitted information will be publicly disclosed
- No mandatory requirement

- Performance Certification* System

- Optional performance certification via accredited institutions for high-quality products
- Upon company request

* Certification Benefits:

- ✓ Official certification mark
- ✓ Research use in medical institutions (potential pathway toward medical device)
- ✓ Certified data may support future medical device development (e.g., sport/leisure heart rate data → disease diagnosis)



■ Digital Medical Devices Act – Key Update

2. Implementing Regulations under the Digital Medical Products Act

- ❖ **Guideline on Classification and Grading of Digital Medical Devices** (Issued, Nov 6)
 - Reflects new classification criteria tailored to software-specific characteristics
 - Includes practical examples

- ❖ **Guideline on Labeling of Digital Medical Devices** (Issued, Nov 6)
 - Covers electronic labeling guidance for medical device software
 - Specifies labeling guidance for AI-based medical devices

- ❖ **Guideline on Manufacturing and Quality Management for Digital Medical Devices** (Issued, Nov 12)
 - Outlines QMS establishment and operation focused on software devices and AI-based technologies

- ❖ **Guideline on Cybersecurity for Electronic Intrusion in Digital Medical Devices** (Issued, Nov 12)
 - Sets lifecycle cybersecurity requirements applicable to manufacturers and importers



■ Digital Medical Devices Act – Key Update

3. Guidelines under the Digital Medical Products Act

- ❖ **Guideline on Clinical Trial Design for Digital Therapeutics** (Revised: Oct 31)
 - Provides guidance on sample size calculation and endpoint selection
 - Clarifies criteria for clinical significance in clinical trial design

- ❖ **Q&A on Usability for Approval of Digital Medical Devices** (Issued: Nov 4)
 - Presents practical examples on usability data submitted for marketing authorization of digital medical devices

- ❖ **Guideline on Safety, Performance, and Clinical Trial Protocol for Digital Therapeutics for Substance Use Disorders** (Issued: Dec 29)
 - Establishes safety and performance evaluation methods for digital therapeutics for substance (narcotic/drug) use disorders

- ❖ **Guideline on Safety, Performance, and Clinical Trial Protocol for Digital Therapeutics for Speech Disorders** (Issued: Dec 29)
 - Establishes safety and performance evaluation methods for digital therapeutics designed to improve post-stroke dysarthria



Thank You!

