



REPUBLIC OF KOREA MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the Korean market.

START HERE: WHAT IS THE PRODUCT IN KOREA?

1 Confirm the Korean regulatory identity

Confirm the intended purpose, technology, and claims of the device. Determine whether the device is active, software, implantable, sterile, electrical, or invasive, as these attributes influence classification and applicable requirements under MFDS.



 **Intended purpose / technology**

 **Active / software / implantable / sterile**

 **Electrical / invasive**

 **Claims**

2 Choose the regulatory route

CLASS I



Lowest risk

Low risk devices with established safety. Notification or reporting is typically sufficient.

CLASS II



Moderate risk

Moderate risk devices require stronger review or certification by MFDS before marketing.

CLASS III



High risk

High risk devices require premarket approval with comprehensive technical documentation and evidence.

CLASS IV



Highest risk

Highest risk devices require the strongest review, including extensive clinical evidence and controls.

3 Build the Korean market-access infrastructure



MFDS framework

Understand the Medical Device Act, MFDS regulations, and notices relevant to your device class and pathway.



Korea License Holder / local importer

Appoint a Korea License Holder (KLH) responsible for registration, submissions, vigilance, and post-market obligations.



KGMP / quality expectations

Align with Korean Good Manufacturing Practice (KGMP) expectations for manufacturing and quality systems.



Approval / listing / UDI readiness

Plan for product approval or notification, device listing/reimbursement steps, and Korean UDI implementation.

4 Build the evidence stack



Administrative

Device description, intended use, tech characteristics, regulatory history, and risk management.



Quality / KGMP

QMS aligned with KGMP and ISO 13485 expectations, including process validation and CAPA.



Safety & performance

Bench testing, software verification/validation, biocompatibility, EMC, stability, and performance evaluations.



Clinical evidence

Clinical data appropriate to device class and risk, including domestic or foreign clinical evidence as applicable.



Labeling / Korean readiness

Korean-language labels and IFU, symbols, warning statements, and packaging per MFDS requirements.



RA TRAP TO AVOID

KGMP expectations, Korea License Holder responsibilities, Korean-language materials, and device-type specifics can change the pathway and timing. Skipping early planning leads to delays and rework.



STRATEGIC INSIGHT:

Early class assignment, clear evidence planning, and strong alignment with your Korea License Holder reduce surprises and accelerate market entry.



REPUBLIC OF KOREA MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch.

A Program flow

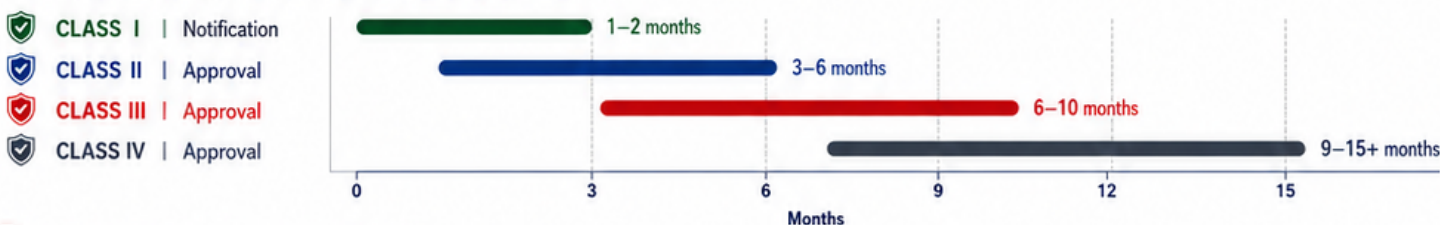


B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III	CLASS IV
Pathway intensity	Notification ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical support	Not usually required ● ● ● ● ●	Limited ● ● ● ● ●	Moderate ● ● ● ● ●	Extensive ● ● ● ● ●
QMS / KGMP readiness	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges

Hopestone planning estimates only — not MFDS promises.



D Labeling & language essentials

Korean labeling
All labels and IFU must be in Korean and compliant with MFDS labeling rules.

IFU readiness
Provide Korean IFU with clear indications, contraindications, warnings, and symbols per MFDS guidance.

Claims control
Claims must be supported by approved indications and evidence for intended use.

License-holder / importer details
AR/importer and manufacturer information must be accurate.

Vigilance / PMS
Maintain PMS, field safety actions, and adverse event reporting per law.

E High-impact Korean decision points

Class I notification vs. higher-class approval
Submission type and documentation scale change significantly by class.

KGMP and quality-site expectations
MFDS inspects quality management systems and manufacturing sites.

Software / connected devices
Cybersecurity, software lifecycle, and data security requirements apply.

Implantable or electrical device implications
Stricter testing, biocompatibility, and electrical safety expectations.

F PRIMARY RESOURCES USED FOR THIS TRAINING AID

- MFDS Medical Devices Information Portal – Overview
<https://med.mfds.go.kr/eng>
- MFDS eGMP System (Application & Submission)
<https://emed.mfds.go.kr>
- MFDS Medical Device Legal System & Guidelines
<https://www.mfds.go.kr/eng/index.do>



IMPORTANT

Current product-specific Korean requirements and MFDS guidance govern.
Confirm classification, evidence, labeling, and submission obligations before execution.