



# Regulatory Update on Medical Devices in South Korea

**Dr. Jeong-Rim Lee**

AHWP TC co-chair

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Ministry of Food and  
Drug Safety





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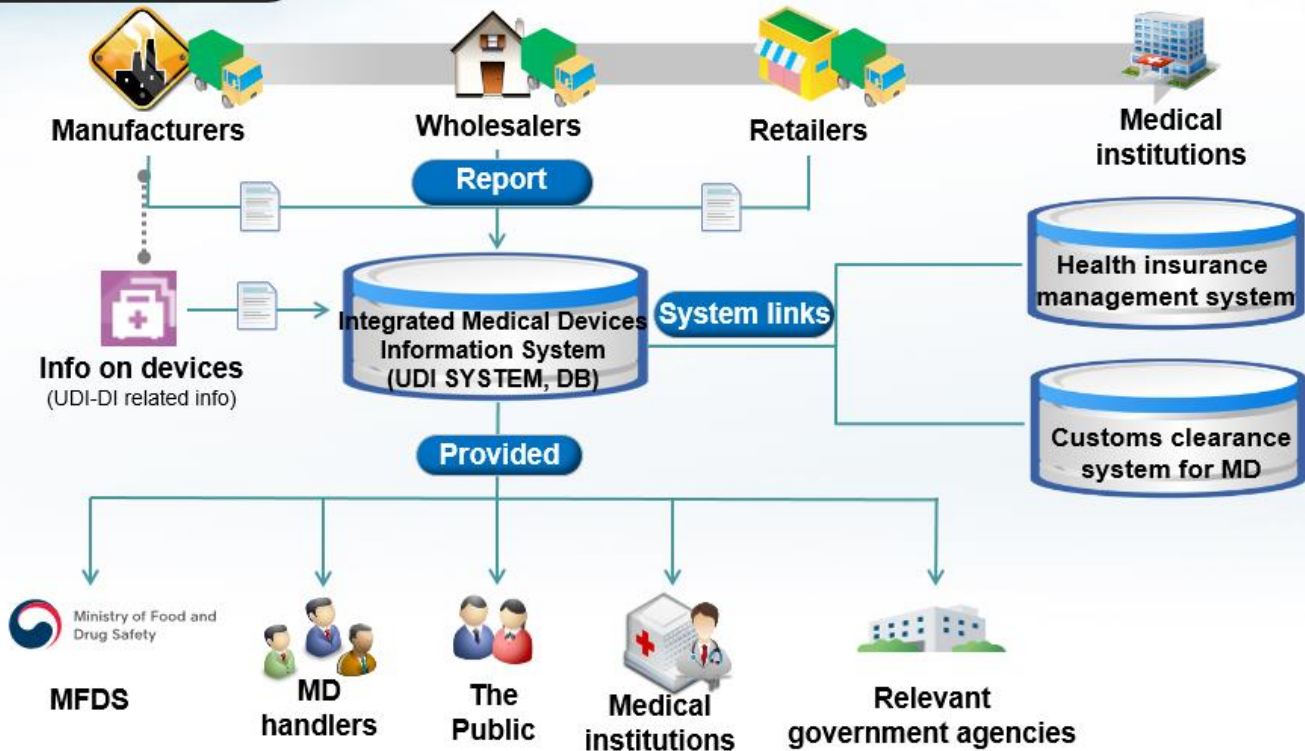
Major achievements & in 2021

## Regulatory Support for COVID19 IVDs

- **(Official Approval)** EUA and Official approval of export products
  - 67 cases of official approvals including EUA approved IVDs expired ('21.2.1)
- **(Quality Management)** Provide consulting including quality management on monitoring of IVDs manufacturing sites, etc
  - \* Offer relevant consultation on manufacturers' difficulties and their clinical performance trials, respectively
- **(Clinical Performance)** Support clinical performance evaluation by liaising between manufacturers and hospitals

# UDI System for Medical Devices

## Overview of UDI System in Korea



- Implemented starting from class 4 devices as of July 2019 and fully implement to all devices by 2022, July.

## Management of Innovative Medical Devices

- **(Designation)** Continuing designation and reviewing its application (**Designated: 16**)
  - MLMDs, robotic surgical system, focused ultrasound stimulator system, and SaMD, etc.. have been newly designated since 2020 May.
- **(Further Progress)** Reinforcement of Innovative Devices
  - Improve evaluation system including review criteria for ensuring fairness of the device assessment
  - Strengthen consulting and priority review, throughout the TPLC for marketing authorizations
  - Introduce customized education for developing the devices and boosting regulatory expertise

## Extension of Terms in the Nomenclature for Medical Environment

- **(Purpose)** To expand terms in the current nomenclature system to go along with the medical environment shifts and technology innovations
  - Necessary to keep up with the emerging trend in the medical device industry to be aligned with the 'Medical Field Digital Transformation'
  - \* (e.g.,) Emerging technologies such as Artificial Intelligence, Big Data, AR·VR, and so forth
- **(Strategies)** To establish new items to expand the scope of safety for medical devices
  - \* (e.g.,) Launching new terms for devices novel technologies like software using virtual augmented technology for surgical procedures simulation on screen, and so forth

## AI(Artificial Intelligence) Medical devices, SaMD approval status ('21.Nov)

### ➤ Machine Learning Medical Devices



**88**: MLMD approved

**53**: Clinical trial protocol approved  
(MLMD related)



### ➤ Digital Therapeutics(DTx)

**8**: Clinical trial protocol approved (SaMD only)





## To Simplify Regulatory Requirements of SaMD

- Streamlined facility standards of SaMDs manufacturing sites

Item	Revision
<b>For SaMDs manufacturing facilities</b>	<b>Waiving the concept of place</b> (Sites, Facilities, Laboratory, Warehouse... etc..)
<b>Changes</b>	<b>For location changes</b> - Exempt the changes of manufacturing site of SaMDs

A photograph of a modern, multi-story building with a light-colored facade and large windows. The building is partially obscured by a semi-transparent blue rectangular overlay. The sky is a pale, clear blue. In the foreground, there are some bare trees and a street lamp.

02

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Guidance Update

## Developed Guidances for Industry

### COVID-19

- Guidance on the Review & Approval of IVDs for COVID19(4th Edition)

### Premarket

- Guidance on the Review & Approval of Power-Assistance Device for Wheelchair
- Guidance on the Review & Approval of Medical Device with Virtual Reality and Augmented Reality Technology(2<sup>nd</sup> Edition)
- Guidance on the Review & Approval of Digital Therapeutics Medical Device
- Guidance on GLP Considerations for Biocompatibility Test
- Guidance on Clinical Performance for IVDs
- Guidance on the Review & Approval of Medical Respirator

### GMP

- Guidance on the Usability of Biomaterial for Graft / Prosthesis
- Guidance on the Usability of Robotic-guidance Rehabilitation Exerciser

### Post -market

- Manual for Reducing Foreign Object Debris of Syringe

Thank you



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