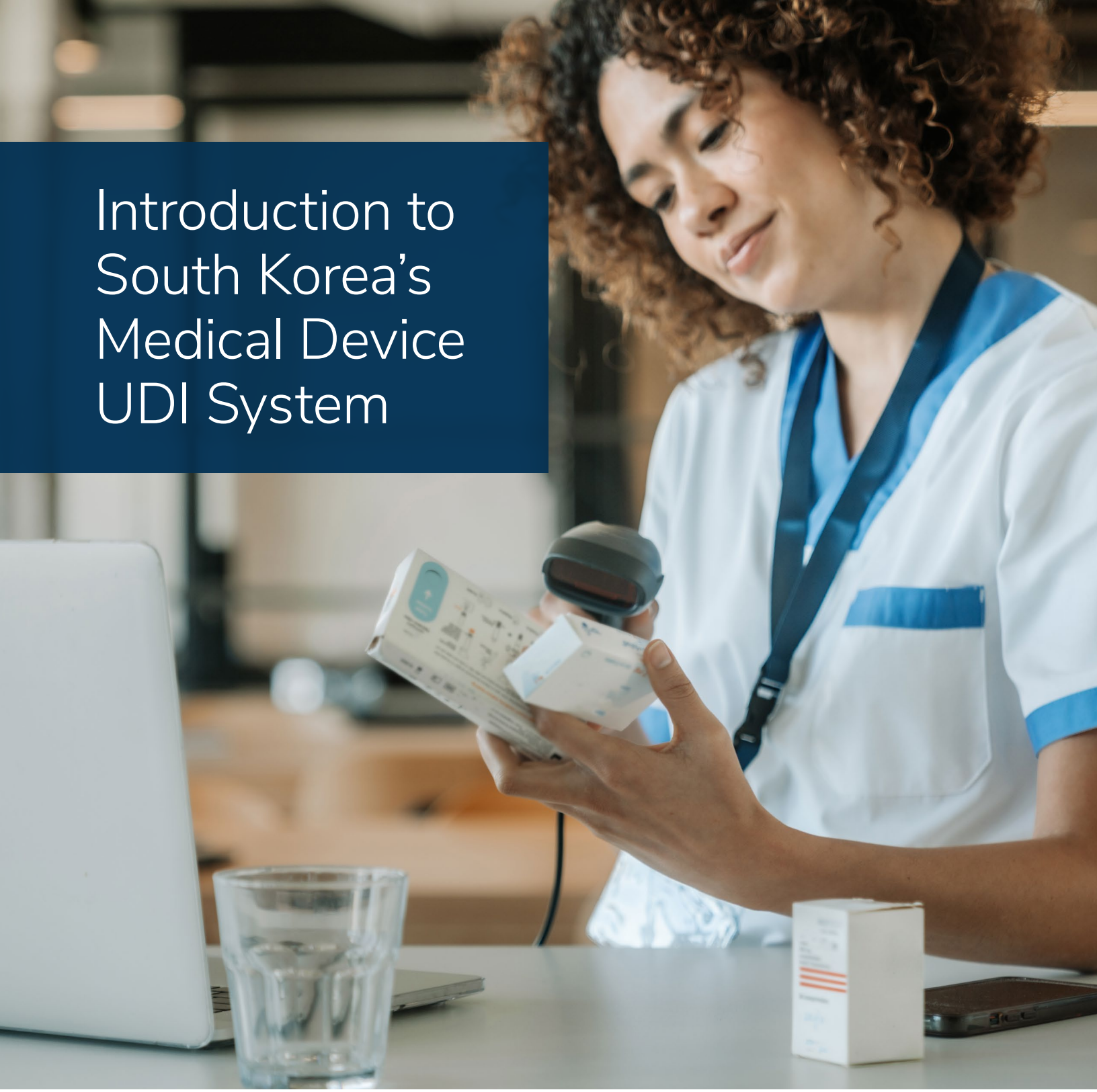

Introduction to South Korea's Medical Device UDI System

JaeYeong Noh
Lead Quality and Regulatory Affairs Consultant
jaeyeong.noh@ul.com

EMERGO
by UL

June 2024

Executive summary

The South Korea Ministry of Food and Drug Safety (MFDS) issued Unique Device Identifier (UDI) requirements on December 21, 2018 (MFDS notification No. 2018-109). The latest UDI rule is MFDS notification No. 2023-67. It has been implemented into Article 20 of the Medical Device Act (No. 19655) and Article 54-3 of the Enforcement Regulations of Medical Device Act (No.1946). UDI compliance for all devices is now mandatory.

This white paper will discuss the basics of the regulation, key points to consider and recommended preparations to support proper implementation of a UDI system.

What is the purpose of UDI?

This regulation encompasses various MFDS concepts to provide safer and more effective products to the public. The UDI system's final rule provides standard device identification and accompanying information to support public health initiatives, such as the MFDS post-market surveillance (PMS) requirements.

The MFDS enumerated several reasons for the UDI regulation, including:

- Reducing medical errors caused by healthcare professionals using the wrong device
- Rapidly identifying a medical device for distribution information (Article 31-2 Report, etc. on Details of Supply of Medical Devices on Medical Device Act)
- Rapidly deploying, identifying and resolving recalls or market corrections
- Ability for manufacturers to develop solutions to device issues by identifying finished medical devices
- More effective communication with the MFDS for device identification
- Establishing and operating an electronic data processing system (after this referred to as "integrated medical device information system") to efficiently record and manage information on medical devices, including approval, manufacture, import, sale and use

The UDI system is the key to accessing a wealth of information about medical devices worldwide. It generates a number that can be attached to each medical device for quick identification. The UDI number identifies the labeler and specific product information and ties into a database that provides even more detail on the important features of that device.

The UDI regulation from MFDS requires that all medical devices have UDI numbers located on their packaging and/or directly marked on the device, with few exceptions. The UDI must be in plain text (human-readable interpretation (HRI)) and encoded in barcode form (or including Radio-Frequency Identification (RFID)).

Domestic manufacturers and importers in South Korea must enter UDI device identifier (UDI-DI) information into the MFDS's integrated information system of medical devices (IMDIS) before distributing their product. The IMDIS only requires companies to provide information on the device identifier (DI) and the general type of production identifier (PI) included in the labeling — not the actual production identifier for every device manufactured.

What devices need to be directly marked with UDI, permanent UDI?

Medical devices intended for more than one use (reusable); reprocessed for continued use (reusable); designated and published separately by MFDS; or that can be separated from their packaging before use (for example, requires sterilization or other treatment before use) require direct permanent UDI marking on the device itself. This confirms that products are durable and that devices used more than once can be readily identified at any time during the product's life.

However, MFDS has not yet determined the related classification code for permanent UDI marking. If MFDS officially designates the specific classification code, manufacturers must comply with permanent UDI directly marking on the device according to Article 5 paragraph 2 of Unique Device Identifier (UDI) requirements (MFDS notification No. 2020-29).

If medical device software is supplied intangibly (e.g., cloud-based or downloaded from a cloud-based source) rather than as a hard copy (e.g., via diskette or CD), the UDI could be provided in a way that users can check after installing the standalone software.

How does UDI work?

The application of the UDI number assignment may be difficult. The MFDS has designated the composition of the UDI-DI and UDI-PI, utilizing the GS1 system. In addition, the MFDS has assigned the National Institute of Medical Device Safety Information (NIDS), as responsible for the implementation of UDI.

What is the Global Trade Item Number, UDI-DI (GTIN)?

GTIN is a standard code system developed by GS1, which allows the industry to globally identify goods in the supply chain. The GTIN 14 is generally used for UDI-DI of medical devices registered to the MFDS. GTIN 14 could consist of GS1 code (country code and company code), product code, check digit and logistics code.

For example, GTIN 13 of UDI-DI is the retail unit of the product in the market. This consists of 13 digits:

1. Country code (880)
2. Company code (between four and six digits)
3. Product code (between three and five digits)
4. Check digit

On the other hand, GTIN 14 of UDI-DI is the logistics (distribution) unit in the market, with an additional digit to the GTIN 13.

Table 2: Example of GTIN 14(UDI-DI) composition

Logistics Code	GS1 Code (Country Code + Company Code)									Product Code			Check Digit
	Country Code			Company Code									
1	8	8	0	8	6	0	4	4	4	0	1	0	7

Source: South Korea National Institute of Medical Device Safety Information (NIDS)

What are application identifiers, UDI-PI (GS1 AI)?

GS1 AI (UDI-PI) supplies additional information, such as expiration date, lot number and specification (e.g., software version) in the barcode. This application identifier (AI) indicates between two and four digits in front of additional information as an identifier on the barcode:

- 01 – Indicates the following 14 digits are the product identification code, GTIN.
- 10 – Indicates the following information is a lot number; the data format could be alpha-numeric, up to 20 digits
- 11 – Indicates the following information is a production date (and the order should be year, month and day. If only year and month information exist, the day must be shown as "00."
- 17 – Indicates the following six digits comprise the expiration date; the order should be year, month and day. If only year and month information exist, the day must be indicated as "00."
- 21 – Indicates the following information is a serial number; the data format could be alpha-numeric up to 20 digits

Application Identifiers (AI)	Meaning of Information
01	GTIN (Global Trade Item Number)
10	Lot Number
11	Production Date (YYMMDD)
17	Expiration Date (YYMMDD)
21	Serial Number

According to Article 4 paragraph 2 of the Regulation on the Unique Device Identifier (UDI), MFDS Notification, No. 2023-67 if any of the following changes occur, regeneration of the UDI is required.

1. Transfer of product license, excluding business license, for a domestic manufacturer
2. Packaging unit
3. Information related to disposal or product sterilization

As mentioned above, some changes to device packaging may require a new UDI. The MFDS contends that the identification of the device needs to be known throughout distribution and use. The company must define a good rationale for not assigning a new UDI number if aspects of the packaging are changed. Further, the company's change management process must identify changes through the entire packaging level and the device itself.

The Unique Device Identification System guidance states that all dates "intended to be brought to the attention of the user" must be in all-numeric format. According to the UDI regulation, the mandated format for manufacturing and expiration dates must be YYMMDD; as an example, Jan. 15, 2020, would be formatted as 200115. Without a specific date, the date (DD) must always be indicated as "00."

Changing the date format will be a challenge for many companies. This requirement may confuse healthcare professionals in South Korea and other countries where DD-MM-YY format is common. When presented with the date 2019-06-07, there could be confusion—is that June 7, 2019, or July 6, 2019? Medical device manufacturers are encouraged to prepare their customers for these changes. Otherwise, manufacturers may receive complaints, such as "Used beyond expiration date," that could easily be avoided with some preemptive explanation.

UDI components

The actual UDI number consists of two parts: the device identifier (DI), the static information assigned by foreign manufacturer (Using GS1 website in their country) or KoreanNet (**www.GS1KR.ORG**) for domestic manufacturers or importers in South Korea; and the production identifier (PI), which is considered the "dynamic," variable information, including serial/lot number and expiration/manufacture date. The labeling organization can determine what information could be included in the PI depending on the medical device, whether the device is disposable or reusable, and the packaging configuration.

Class I devices do not require the PI as part of the UDI. Therefore, Class I devices only require the DI portion. Although PI is not required for Class I devices, the labeler can include PI information for their internal requirements.

On the device packaging, the UDI number (composed of either the DI or the DI and PI) must include numbers or letters that are in human-readable form and a barcode or (including RFID tag).

All devices that must comply with the UDI requirements should contain a device identifier (DI).

The table below is a summary of the final UDI (DI + PI) with an example, and the following figure (Figure 2) is an example of the final MFDS label with UDI.

Consist	UDI-DI						UDI-PI					
Contents	Information related to the device • Manufacturer Country • Manufacturer/Importer • Product Code, etc.						Information related to production • Lot or Batch Number • Expiration Date • Production Date • Serial Number, etc. • Version information(in case of software medical device)					
GS1 code	**GS1 AI (Application Identifier) Code : Class 2 - 4 of medical device**											
		GTIN-14 : Class 1										
Example	AI	Logistics Code	Country Code	Company Code	Product Code	Check Digit	AI	Lot No.	AI	Expiration No.	AI	Serial No.
	01	0	880	12345	1234	3	10	110500	17	120501	21	9G837GH
	UDI: (01)08801234512343(10)110500(17)120501(21)9G837GH											

Legible numbers or letters under the barcode of the UDI may be omitted under the following circumstances according to Article 5 paragraph 4 of MFDS notification No. 2023-67:

- When using the GS1 Datamatrix according to Annex 2.
- When the size of barcodes is the same or smaller than containers or enclosures according to Annex 3

MFDS also clarifies acceptable attachment methods of barcode and RFID tags as the following:

1. European Article Number-13 barcode, GS1-128 barcode, or GS1 Datamatrix barcode should be used in the GS1 (Global Standard #1) system.
2. SGTIN (Serialized Global Trade Item Number)-96 or the SGTIN (Serialized Global Trade Item Number)-198 for RFID tag should be used in the Global Standard #1 (GS1) system.

Notwithstanding Article 4 (1), Articles 6, and 7 of MFDS notification No. 2023-67, a medical device manufacturer or importer may generate and label a UDI by utilizing an international standard system that falls under any of the following according to Article 8 (Special Cases conserving UDI):

1. Health Industry Business Communications Council (HIBCC)
2. International Council for Commonality in Blood Banking Automation (ICCBBA)

Once the UDI code is generated and attached to the medical device and/or packaging, UDI-DI information must be listed on the Integrated Information System for Medical Devices by a domestic manufacturer or importer before distributing the product in South Korea, according to Article 54-3 (Operating the integrated information system of medical device, etc.) of the Medical Device Act Enforcement Regulation. The listing should include:

1. Information regarding UDI
2. Information regarding the medical device (including information on the approval, certification, and notification of the medical device)
3. Information about the domestic manufacturer and importer of the medical device (including foreign manufacturer)

UDI compliance to-dos

1. Read the MFDS UDI **final rule**.
2. Read the **guidance** of the Unique Device Identification System.
3. Read the **guidance** for how to label the barcode.
4. Establish and implement a Unique Device Identification (UDI) System procedure in your quality system and assign roles to manufacturers and/or importers to take responsibility for UDI compliance in South Korea.
5. Understand your global device's distribution. Stay aware of key differences between the South Korean UDI System and UDI systems in other countries to apply a harmonized UDI approach.
6. Train employees on UDI requirements, regulations and new procedures for South Korea, and document and keep records of this training.
7. Assemble and designate the project team or core team, which should include a cross-functional team representing marketing, production, quality, regulatory, and development. Assign UDI tasks to personnel to tackle the transition and address the ongoing maintenance tasks.
8. Evaluate labeling-related equipment (e.g., printers, scanners, etc.) for appropriate capabilities. Update or replace as needed. Identify any equipment installation or qualification requirements.
9. Define and list whether all your devices are required to generate a UDI per model or package unit.
10. Generate GTIN (UDI-DI) to each model, product name, and package unit and then create and manage UDI-PI as well.
11. Update the product labeling with the UDI number or letter in human-readable format.
12. Assign identification information to your devices.
13. Communicate the information on the new UDI labeling and how to use it within your organization and throughout your distribution channels.
14. If the medical device is manufactured by a domestic manufacturer or the date of customs clearance to South Korea surpasses the UDI enforcement date, domestic manufacturers or importers must register the medical device's information (UDI-DI) in the **integrated information system (IMDIS)** of the MFDS web interface.

Conclusion

The MFDS Unique Device Identification Regulation provides a way for patients, users and healthcare professionals to identify any medical device they are using. As this is still a new regulation in South Korea, the regulation has not provided much clarification. Therefore, to provide guidance, NIDS has been issuing guidance for special cases, such as during emergency surgeries where there may be a need to extract already sterilized devices from different sets to assemble them into a set (stainless steel box) appropriate for the specific case.

Therefore, Emergo by UL recommends that manufacturers carefully review the UDI regulation and the related guidelines to confirm there is a strategy to implement the current UDI requirements within their organization. In addition, it is important to confirm that other entities involved in the distribution of devices are familiar with the UDI requirements as well.

End Notes

1. Unique Device Identification System — MFDS Final Rule (Notification No. 2023-67)
2. Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI) - Guidance for Industry (December 28, 2018)
3. Unique Device Identification: Medical Device Barcode Marking Guidelines - Guidance for Industry (December 28, 2018)

Learn more

Need help with new UDI regulations for South Korea? Emergo by UL supports regulatory compliance and market access for device manufacturers worldwide. Here's how we help:

- South Korea MFDS medical device registration consulting
- South Korea KGMP quality management system consulting
- Korea License Holder in-country representation

Learn more about global market access for medical devices at **EmergobyUL.com**.

About the author

JaeYeong Noh has over 14 years of industry experience, primarily focused on high-risk devices such as disposable medical materials and electrical products. Based in Seoul, South Korea, she is one of our key contacts for MFDS inquiries and also possesses in-depth experience with KGMP applications, including auditing for initial registration approvals, renewals, and modifications. JaeYeong held previous roles as a medical device technical reviewer at MFDS and RA positions at Olympus Korea. She has peer reviewed more than 100 regulatory filings and reports.

EMERGO

by UL

CS1620850