Global Unique Device Identification Considerations for Medical Device Manufacturers

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by UL

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An Introduction to UDI Regulations

The U.S. Food and Drug Administration (FDA) issued its Unique Device Identifier (UDI) rule in September 2013. The FDA UDI rule is now fully implemented and was adopted to provide a range of benefits to the medical device industry.

These include:[1]

- Allowing more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly
- Reducing medical errors by enabling healthcare professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device
- Enhancing safety analysis of devices on the market by providing a standard way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust post-market surveillance system can also be leveraged to support clearance or premarket approval of new devices and new uses of currently marketed devices
- Providing a standardized identifier that will allow manufacturers, distributors and healthcare facilities to better manage medical device recalls
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies
- Leading to the development of a medical device identification system recognized worldwide

Similar systems are being developed in other markets to develop a globally recognized system of device identification.

The UDI identifies the labeler and information that is specific to a product, and ties into a database that provides even more detail and important features of that specific product. This involves UDI numbers located on packaging and/or directly marked on the actual device, with limited exceptions. The UDI must be in both plain text (human-readable interpretation/HRI) and encoded in the form of automatic identification and data capture (AIDC) technology, such as a barcode or radio-frequency identification (RFID).

Various UDI systems require entering information about the product into a publicly accessible database. This database allows hospitals, clinics and healthcare professionals to look up the identification information for medical devices available in any country that has adopted a UDI system. The information entered also includes attributes or data elements and identifies information about the device such as its marketing clearance, classification information, package configurations, clinically relevant sizes and information found on the labeling. Some systems, such as the one in the European Union, incorporate a Basic UDI-DI. This identifies product groupings by categories, such as classification, intended use, materials and manufacturing methods. The databases only require companies to provide device identifiers and the general type of production identifier included in the labeling — not the actual production identifier for every individual device manufactured.

The databases used in countries that have UDI requirements require that information is kept up to date. If new products or new models are introduced, these require a new entry into the databases. The same is true if there are configuration changes or corrections to the previous entries.

There are various issuing agencies accredited by the regulatory bodies in countries that are implementing UDI in their jurisdictions. When companies are considering issuing agencies, it is important to verify with the regulatory bodies in the various countries where agencies are allowed. The following chart gives some information on the current state of UDI. It is important to note that this is an evolving area; therefore, the status of UDI implementation should be verified in each country where a company intends to market its devices.

Table 1 – Status of UDI by country – current as of April 2024.

Country	Regulatory body	Effective date	Implementation schedule	Framework and database
Australia	Therapeutic Goods Administration (TGA)	February 2021	To be determined (delayed in May 2023)	Submit UDIs to the Australian Database of Medical Devices (AusUDID)
Brazil	ANVISA	January 2022	To be determined, but will have six-year rollout following the publication of subsequent normative instruction	IMDRF Database in process based on GS1, HIBCC, ICCBBA
Canada	Health Canada	To be determined, proposal issued in June 2021	To be determined	IMDRF Proposed UDI database
China	NMPA (China National Medical Products Administration)	August 2019	Currently required for Class III and some Class II devices. Phased rollout for remaining devices.	NMPA UDI Database. Code agencies are GS1 China, ZIIOT, and Ali Health Technology (China) Co.
Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	August 2022	Phased implementation based on classification. Compliance deadlines are as follows: Class III - February 2025 Class IIb - August 2025 Class I and IIa - February 2026	INVIMA UDI Database in development. Code-issuing agency must be authorized by the U.S. FDA.
India	Central Drugs Standard Control Organization (CDSCO)	Framework established in December 2021, but effective date to be determined	To be determined	Future UDI database
Japan	Ministry of Health, Labor, and Welfare (MHLW) Pharmaceuticals & Medical Devices Agency (PMDA)	December 2019	Required since December 2022	GS-1 standard Japan Medical Devices Information System (J-Med Net)

Taiwan	Taiwan Food and Drug Administration (TFDA)	May 2021	Required for Class II and III devices since February 2024	Taiwan UDI Database (TUDID). Based on U.S. FDA UDI requirements.
EU	European Commission	With MDR and IVDR April 2021	To be determined. Delayed due to COVID and EUDAMED delays	IMDRF, MedTech Guidance EUDAMED database
Egypt	Egyptian Drug Authority (EDA)	December 2021	Global Trade Item Numbers (GTINs) required since November 2022	GS1 or advise EDA regarding issuing agency
Saudi Arabia	Saudi Food and Drug Administration (SFDA)	September 2020	Required for Class B, C and D devices since September 2023 Required for Class A devices by September 2024	Saudi database SAUDI-DI available since Oct. 1, 2020
Singapore	Health Sciences Authority (HSA)	August 2021	Phased for Class D, C and B through 2028 No requirement for Class A	IMDRF – EU and U.S. labels OK for Singapore; Singapore Medical Device Information Communication System (MEDICS)
South Korea	Ministry of Food and Drug Safety (MFDS)	June 2019	Required for all classes since July 2022	IMDRF Integrated Medical Device Information System (IMDIS)
Turkey	Turkish Medicines and Medical Devices Agency (TiTCK)	2017	UDI Marking currently required	Follows EU MDR guidelines. Ürün Takip Sistemi-Product Tracking System (ÜTS) where manufacturers are required to register their medical devices and their UDIs
U.K.	Medicines & Healthcare Products Regulatory Agency (MHRA)	January 2021	To be determined	In development
U.S.	U.S. Food and Drug Administration (FDA)	September 2013	Fully implemented	Initial requirements stated in the data elements table GUDID database

As can be seen from the information in the above table, some countries have varying requirements for the classes of devices and UDI requirements. Each database contains guidelines for what attributes and data elements are to be included in the database. For guidance on applying attributes for the EU, and when assigning the Basic UDI-DI, the MedTech Europe Guidance Document dated June 2, 2020, provides common elements to consider.[2]

A full comparison of Basic UDI-DI and UDI-DI attributes is provided, albeit the latest is the April 2019 version.[3]

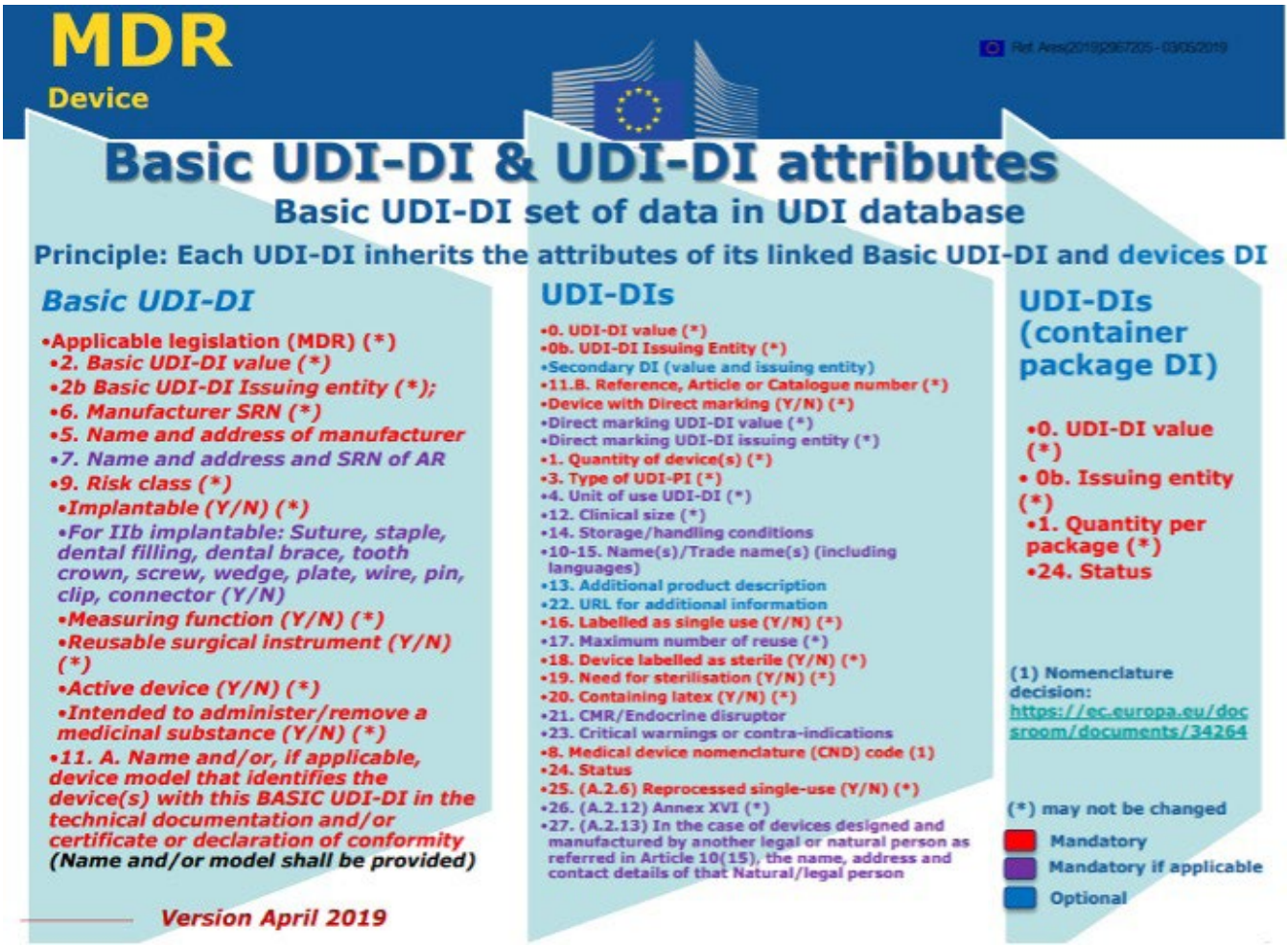

Figure 1 – example of the type of data included in UDIs

This document portrays the data type for elements that most jurisdictions require, although there are some differences in the requirements to report to the databases. The FDA Data Reference Table can be located online.[4] It is updated periodically, so it is a good idea to check for the most recent version when using it to prepare for submission to the GUDID.

The International Medical Device Regulators Forum (IMDRF) final guidance provides the framework that many countries have taken into account when developing their UDI requirements.[5] In the guidance document Appendix A, the standards used by the common issuing agencies, GS1, HIBCC and ICCBBA are presented:

1. GS1 Standards

Issuing Agency/Entity	Qualifier	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI	Numeric	18 (incl. identifier + data delimiter)	14
GS1	(11)	Manufacturing/ Production Date	Numeric [YYMMDD]	10 (incl. identifier + data delimiter)	6
GS1	(17)	Expiration Date	Numeric [YYMMDD]	10 (incl. identifier + data delimiter)	6
GS1	(10)	Batch/Lot Number	Alphanumeric	24 (max) (incl. identifier + data delimiter)	20 (max)
GS1	(21)	Serial Number	Alphanumeric	24 (max) (incl. identifier + data delimiter)	20 (max)
GS1		***Maximum Base UDI***	***To be determined***	***86***	***66***
ex: (distinct 01)09506000117843(11)141231(17)201231(10)1234AB(21)5678CD					

2. HIBCC Standards

Issuing Agency/Entity	Qualifier	Identifier	Data type	Human Readable Field Size	Database Field Size
HIBCC	+	UDI-DI	Alphanumeric	7 to 24	6 to 23
HIBCC	$	Lot Number Only	Alphanumeric	19	18
HIBCC	$$7	Lot Number Only (alternative option)	Alphanumeric	21	18
HIBCC	$$	Expiration Date followed by Lot Number	Exp. Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	$$2	Expiration Date followed by Lot Number	Exp. Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$3	Expiration Date followed by Lot Number	Exp. Date: numeric [YYMMDD]	9	6
ex: *+H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ4567890123 45678/16D20130202C*					

Note: Additional configurations are found in the Appendix A

3. ICCBBA Standards

Issuing Agency/Entity	Qualifier	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	UDI-DI	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Donation Identification Number	Alphanumeric	16	15
ICCBBA	=>	Batch/Lot Number	Numeric [YYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	Numeric [YYYJJJ]	8	6
ICCBBA	&, 1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		***Maximum Base UDI for HCT/Ps***	***Alphanumeric***	***79***	***67***
Example of Human Readable Barcode: =)1TE123456A&)RZ12345678					

Figure 2 – GSA, HIBCC and ICCBBA UDI construction information

In general, there are exceptions to some of the UDI requirements.

Some categories and device types are exempt from UDI regulations. This can vary from country to country, therefore, review the latest requirements when preparing to report information to UDI databases:

- For U.S. FDA, Class I devices (and only Class I) that have a UPC number and barcode assigned are not required to obtain UDI numbers.
- In some countries, Class I devices are exempt from reporting, while they are required in other countries.
- Custom devices, research use only and investigational devices that fall under 21 CFR Part 812 in the U.S. are not required to obtain UDI numbers.

Note that if a medical device is a single-use or homogenous product bundled into a single package until removed for use, such as a box of gloves, adhesive bandages, solutions in bottles or gels, that device only requires a UDI number on its packaging. Further exemptions from the UDI regulation may be requested from the applicable regulatory agency based on the company's needs or possible technological features of the device that would make UDI placement difficult.

Software-only products must also contain UDI numbers either in their opening dialog or their "About" screens. This may present challenges for companies with multiple SKUs, multiple part numbers or multiple packaging configurations for their devices.

Manufacturers must consider the impact on the device's UDI number when introducing device changes (e.g., a new model, changes to the device packaging or changes to the "look" of the device). Many companies already have a change management system, but they must also establish criteria for the impact on UDI numbering and new assignments.

The UDI requirements in the final rule have requirements that dates "... intended to be brought to the attention of the user..." must be in the all-numeric format. According to the UDI regulation, the mandated date format for manufacturing and expiration dates must be in the numeric format, YYYY-MM-DD; as an example, Jan. 15, 2020, would be formatted as 2020-01-15. A day (DD) must always be included.

Implantable devices do not require UDI marking directly on the device.

All devices that must comply with the UDI requirements must contain a Device Identifier (DI).

UDI components

The actual UDI number is separated into two parts: the device identifier (DI), which identifies the labeler and the device model, and the production identifier (PI), which is considered the "dynamic," variable information, including such things as serial/lot number, expiration/ manufacture date, package configuration. These items are variable according to the needs of the organization, or perhaps other regulatory requirements for the type of devices manufactured.

On the device packaging, the UDI number (composed of either the DI or the DI and PI) must be in both automatic identification and data capture (AIDC) format, such as a barcode, and in human-readable form. An example of a UDI number in both AIDC and human readable form is shown in Figure 3.

The UDI must be applied at all levels of packaging, from the direct device label to unit-level packaging and the numbers will be different for each packaging level. For instance, if the device is sold in cases and by pallet, the case has a different UDI number from the single device, and the pallet has yet a different UDI number. The UDI number does not need to be on the shipping box. When direct marking of the UDI number on the device is required, it must be in AIDC and human-readable format. This might be a challenge for companies requiring direct marking that cannot be in the form of labels or tags. Again, the main purpose of the UDI is to have a unique identity for rapid identification of a finished medical device.

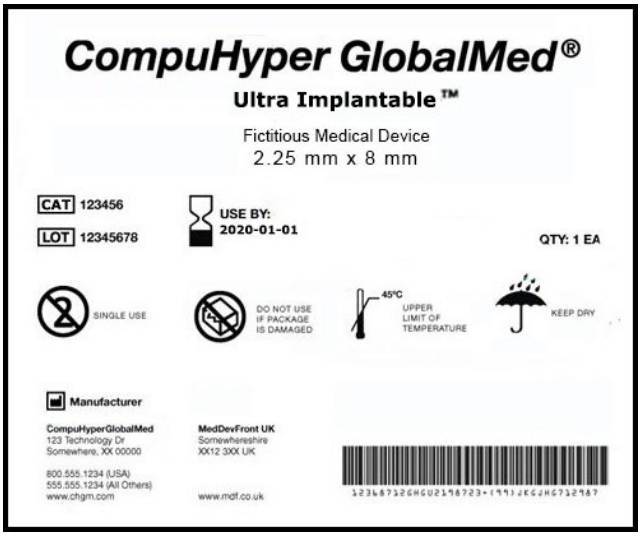

Figure 3 – An example provided by the U.S. FDA

Once a manufacturer has determined the model or version groupings for its medical devices, the firm will then contact an issuing agency to obtain the UDI format and will assign the number based on the labeler ID assigned by the issuing agency, the device identification and any variable information will be identified during the labeling process. There are currently three issuing agencies accredited by the FDA, and most other countries recognize these as well, although some have various other country programs in place. There are some other agencies identified in some of the countries. Therefore, the UDI requirements by country should be reviewed.

- **GS1 US** – Lawrenceville, NJ
- **Health Industry Business Communication Council (HIBCC)** – Phoenix, AZ
- **ICCBBA** – San Bernardino, CA

A company selects an issuing agency, completes an application, and pays the applicable fee. As part of the application, the company must provide all of the pertinent information related to product models or versions that will be included in the UDI databases for the countries involved. When reporting UDI information on devices, the UDI databases generally provide either a manual method to add the data or a third-party provider can transmit the information electronically from the third-party provider to the database. To provide the information electronically, special spreadsheets must be prepared that meet the rules of the particular database so the data can be transmitted successfully.

The databases are publicly available to search for a company's product information, manufacturers or other distribution information, and the type of information that applies to the various products (See Figure 1). Database users may also enter a UDI number to look up the applicable information. Not all the data reported to the databases is publicly available.

UDI compliance to-dos

To prepare for UDI compliance, the following steps are provided to help manufacturers:

1. Locate relevant UDI requirements for each market area in which you are interested in placing your devices. Each of the issuing agencies provides helpful information on their websites. For example, the FDA provides the following UDI information:
   - **UDI final rule**
   - **GUDID guidance document**
2. Establish and implement a Unique Device Identification (UDI) System procedure in your quality system.
3. Understand your device's distribution patterns throughout the globe and keep an eye on global implementation steps as they develop for UDI.
4. Train employees on the UDI requirements, the regulations, new procedures and document training on the training records.
5. Assemble and designate the project team or core team, which includes 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.
6. Evaluate labeling-related equipment (e.g., printers, scanners, etc.) for appropriate capabilities. Update or replace as needed. Identify any equipment installation or qualification requirements.
7. Select an accredited agency to obtain your company identification and UDI numbers formats under supplier evaluation procedures to obtain your company prefix.
8. Assign the applicable identification information to devices.
9. Define and list all of the attributes associated with the product versions to be included in the UDI databases into which you will report (e.g., sterile, packaging levels, direct marking).
10. Populate the UDI database, including the UDI number and the attributes defined, according to the methods provided by the individual databases or through a third-party provider.
11. Update the product labeling with the UDI number in human-readable format and AIDC format.

Note: All product versions or part numbers of the finished medical device to which UDI applies will have an assigned UDI number located with direct marking on the product (when required — typically reusable devices), on the product labeling, and/or the product packaging (and packaging levels), unless exempt. Exempt devices must be identified and documented with the exemption rationale, consistent with the regulations.

12. Communicate the information on the new UDI labeling and how to use it both inside your organization and throughout your distribution channels.

Conclusion

The Unique Device Identification regulations worldwide intend to provide a way for patients, users, and healthcare professionals to readily identify medical devices they are using, and to include that information in patient health records. The U.S. FDA's vision for providing a global method to identify devices used for patient care is becoming more of a reality as countries adopt their methods. The issuing agencies are also responding by providing resources and information to assist companies in setting up their systems to respond to regulatory requirements country by country.

UDI information can generally be added to the required databases either by manual web-based entry or by electronic downloads that can be programmed within the company IT framework or provided by third-party suppliers. We at Emergo by UL can help companies prepare for compliance by identifying marketplaces, and individual requirements by country, and by gathering the data necessary for the successful integration of the UDI processes and reporting.

If a company has only a few models or versions of devices, they may find compliance and reporting fairly simple once the system is in place and the procedures are created to maintain the data. A company with numerous offerings or multiple locations will do well to engage project teams to determine the needs to comply and how to accomplish the reporting, site by site. It is important for a company to carefully review the product offering to determine whether there are models that should be discontinued, whether package configurations are reasonable, and whether there are adequate resources in the company to absorb the required work and maintenance.

End Notes

1. https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/benefits-udi-systemhttps://
2. 200602_MTE-Basic-UDI-DI-guidance-v1.1_final.pdf (medtecheurope.org)
3. https://ec.europa/docsroom/documents/35241/
4. GUDID-Data-Elements-Reference-Table_04.27.20.xlsx (live.com)
5. www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf

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About the author

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