



FINAL DOCUMENT

Global Harmonization Task Force

Title: Unique Device Identification (UDI) System for Medical Devices

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This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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Preamble

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1. Introduction

This purpose of this guidance is to provide a framework for those regulatory authorities that intend to develop their own UDI Systems – such that, when implemented, we achieve a globally harmonized approach to UDI. We expect the regulatory authorities to follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a global UDI System, it is critical that these systems are implemented **without** regional or national differences. This guidance is intended to provide a high-level conceptual view of how a global UDI System should work. We recognize that further additional guidance may be needed once these core concepts are implemented.

The fundamental concepts of a global UDI System include:

- The UDI and UDI Carrier are based on global standards
- A UDI applied to a medical device anywhere in the world should be able to be used globally to meet the UDI requirements of any regulatory authority
- National or local identification numbers should NOT be a substitute for UDI
- Regulatory Authorities should not specify how to modify these standards
- The UDI Database core elements should not be modified
- The UDI Database should use the HL7 SPL for data exchange

The UDI System is intended to provide a single, globally-accepted system for positive identification of medical devices. Health care professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a device, its key attributes. The UDID is a designated source for additional information. It is critical to note that the benefits of UDI can only accrue if all stakeholders, from the manufacturer through to healthcare providers and patients, use UDI throughout their system. Therefore, it

is imperative that all stakeholders be educated about the development and use of a UDI System.

A globally harmonized and consistent approach to UDI is expected to increase patient safety and help optimize patient care by facilitating the:

1. traceability of devices, especially for recalls and other field service corrective actions,
2. adequate identification of the device through its distribution and use,
3. identification of devices in adverse events,
4. reduction of medical errors, and
5. documentation and longitudinal capture of data on medical devices.

1. Traceability – the global use of a single identifier (UDI) will facilitate traceability throughout distribution. This is especially important for recalls and other field service corrective actions.

Though the UDI Database does not capture Production Identifiers, it is expected that supply chain partners will capture and use these identifiers. This is critical during recalls and other field safety corrective actions. In addition, the foundational use of UDI can help fight counterfeiting and secure the supply chain for all stakeholders. Traceability includes:

- Record of products from manufacturer to health care provider
- Record of use in patients
- availability of information for direct patient care (implantables)
- record for product recalls
- standard way to input device identification into registries

2. Identification – UDI will facilitate the adequate identification of the device through its distribution and use by providing a single, global identifier that can be used to link and integrate existing government, clinical, hospital, and industry databases. UDI should allow for improved procurement, inventory management, and accounting. The existence of a single device identifier to link disparate data bases should allow creative new medical and business applications, and synergy among those applications.

3. Adverse Event Reporting – UDI will allow industry and regulatory authorities to more rapidly identify devices involved in adverse events. UDIs will be available for inclusion in adverse event reports, allowing greater accuracy in reporting, and more rapid aggregation of related reports. Using this information, Health Authorities can more rapidly collate and analyze problem reports and identify the most-appropriate solution to a particular concern. UDIs will also allow more targeted safety alerts, recalls, and other corrective actions on the specific devices that are of concern.

4. Medical Errors – by providing rapid and electronic access to critical patient safety information relating to the device, the UDI system may help clinicians more safely select and use the proper device for a patient. UDID data could be downloaded by Healthcare organizations to be used for internal checking of safety related information.

5. Documentation – the use of UDI will facilitate and simplify the documentation of device use in various electronic patient records, including electronic health records and registries. UDI should also enable linkages of device information across various systems and across borders. This could help identify device problems and enhance comparative effectiveness.

Other issues that need to be considered for the successful development and implementation of a globally harmonized UDI System include:

- A risk-based approach is essential given the huge diversity of the medical devices
- Kits, systems and other groups of devices need to be managed appropriately.
- The requirements should be phased in over a period of years based on premarket risk class, starting with the highest risk class first, to help to reduce the complexity of implementation.
- All supply chain stakeholders will need sufficient time frames to prepare their systems, processes and staff, for the proper use of the UDI system.

2. Rationale, purpose and scope

2.1 Rationale

There are currently no global definitions of what constitutes a UDI or UDI System. As a consequence, discrepancies between different national approaches do exist and will most likely increase. Common global UDI requirements would offer significant benefits to manufacturers, users, patients, and regulatory authorities. In addition, eliminating or reducing differences between regulators authorities decreases the cost of gaining regulatory compliance.

2.2 Purpose

A UDI unambiguously identifies a manufacturer's specific medical device. A standardized UDI applied to the device or its label, documented in the UDI Database, and used consistently throughout distribution and use should facilitate a number of patient safety benefits, including:

- traceability of devices,
- the identification of devices in adverse events reports and other postmarket safety surveillance activities,
- recalls and other field safety correction, and
- reducing medical errors.

This guidance intends to avoid country-specific requirements regarding the core elements of the UDI System by developing common guidance to:

- create, use and maintain a unique Device Identifier,
- apply a UDI Carrier,
- establish the UDI Database, with a defined list of Data Elements, and
- use a single data exchange standards.

In order to facilitate global traceability, the UDI System should be promoted and used at all levels by all stakeholders, including regulatory authorities, medical device manufacturers, distributors, hospitals, pharmacies, medical professionals, and patients.

This document was not intended to directly address the issues associated with counterfeit devices or to enable better control of purchasing.

2.3 Scope

This document applies to all products to be placed on the market that fall within the definition of a medical device (including accessories) that appears within the GHTF document "*Information Document Concerning the Definition of the Term "Medical Device"*". Other products, such as equipment used for servicing or maintenance a medical device (e.g. power cord, circuit board) are exempt from the requirements of this document.

3.0 References

GHTF final documents

SG1/N29:2005 Information Document Concerning the Definition of the Term "Medical Device"

SG1/N43:2005 Labelling for Medical Devices

SG1/N055:2009 Definitions of the Terms Manufacturer, Authorized Representative, Distributor and Importer Registration and Listing

SG1 (PD)/N65 Registration of Manufacturers and other Parties and Listing of Medical Devices

Automatic Identification Manufacturers (AIM) Global – Direct Part Marking

<http://www.aimglobal.org/technologies/dpm/>

4.0 Definitions

Accessories

Accessories mean an article intended specifically by its manufacturer to be used together with a specific medical device(s), to enable the medical device to be used in accordance with its intended use. [modified draft GHTF definition – revision SG1 N29/R16: 2005]

Automatic Identification and Data Capture (AIDC)

AIDC refers to the methods for automatic identifying objects, collecting data about them, and entering the data directly into computer systems.

Radio Frequency Identification (RFID)

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

UDI System

The UDI System is the framework for the production of a Unique Device Identification (UDI), the application of the UDI on the label or directly on device, and the storage of the DI and additional device related information in a UDI Database.

UDI

UDI means Unique Device Identification. The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI comprises the Device Identifier and Production Identifier.

Note: The word "Unique" does not imply serialization of individual production units.

Device Identifier (DI)

The Device Identifier Is a unique numeric or alphanumeric code specific to a model (or version) of medical device and that is also used as the "access key" to information stored in a UDI Database.

Production Identifier (PI)

The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, manufacturing and/or expiration date.

UDI Carrier

The UDI Carrier is the means to convey the UDI by using Automatic Identification and Data Capture (AIDC) and, if applicable, its human readable interpretation (HRI).

Human Readable Interpretation (HRI)

Human Readable Interpretation is a legible interpretation of the data characters encoded in the AIDC symbol.

Direct Part Mark (DPM)

Direct Part Mark "... is a technology used to produce two different surface conditions on an item. These markings can be created by laser etching, molding, peening, etc."

UDI Database (UDID)

The UDI Database contains identifying information and other elements associated with the specific medical device.

Kits

Kits are a collection of medical products, including medical devices, and other products that are packaged together to achieve a stated intended use, being distributed as a single medical device. This includes procedural packs and convenience kits.

Label

The Label is written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

[GHTF/SG1/N43:2005]

Manufacturer

Manufacturer means any natural or legal person¹ with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). [GHTF SG1/N055] This includes Reprocessors and Remanufacturers that take responsibility for the device and reintroduce it into commercial distribution.

Own Brand/Private Labelers

An Own Brand or Private Labeler relabels a device from a 3rd party with his own name without making any further changes to the device thereby taking responsibility for it as the manufacturer.

Packaging Levels

Packaging levels means the various levels of device packages that contain a fixed quantity of medical devices, e.g., each, carton, case. This does not include shipping containers such as pallets.

¹ The term "person" that appears here includes legal entities such as a corporation, a partnership or an association

5. Guidance for the UDI System

A UDI System comprises 3 parts - 1. The development of the UDI using a globally accepted standard; 2. The application of that UDI on the label or on the device itself; and 3. The submission of appropriate information to the UDID. In order to facilitate a globally harmonized approach to UDI – it is imperative that:

1. In order to achieve traceability (including recalls), it is necessary to require all stakeholders to capture and store the UDI (DI+PI) through distribution and use.
2. The marking of the UDI should be an additional requirement – it does not replace any other marking or labeling requirements.
3. The manufacturer should create and maintain globally unique UDIs on their medical devices.
4. Once the UDI is established on the device or its package, it should never be changed except in the case of reprocessing, remanufacturing, or relabeling.
5. Only the manufacturer can establish the UDI on the device or its packaging. Reprocessors, remanufacturers, Own Brand/Private Labelers are considered the manufacturer of the reprocessed or remanufactured device – and as such are also subject to these requirements.
6. Internationally accepted coding systems managed by global organizations, such as GS1, HIBCC, and ICCBBA, meet the criteria of the UDI and manufacturers shall be permitted to choose which system to use. These organizations have responsibility for maintaining the global uniqueness of their coding systems. It is imperative that these coding systems be adopted and implemented, without national deviations or changes to these global coding systems.
7. In order to accommodate most methods of labeling, marking, and identifying products, the UDI Carrier should not specify any particular AIDC technology. National or regional regulatory requirements shall not restrict methods of AIDC as this will hinder the establishment of a global UDI System.
8. The National/Regional regulation for UDI System shall include a robust process for evaluating and adjudicating applications for UDI exemptions that would exempt certain device types or package levels (including direct part marking) from being labeled with UDI or specific elements in the UDID.

6. The UDI

1. A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDIs.
2. When a UDI is not assigned to the device at the level of its unit of use, then a Unit of Use (UoU) Device Identifier should be assigned, to associate the use of a device with a patient. [for example, a UoU DI would be assigned to an individual electrode when the electrode is distributed in a package of 10 – and lowest level UDI is assigned to that package of 10]
3. Accessories distributed separately need their own UDI.

4. Kits should have their own UDI.
Note: Jurisdictions may differ in their definition of kit. Individual devices within the kit may not need to have a UDI Carrier as long as the manufacturer can identify the individual devices.
5. The manufacturer assigns the UDI to a device following the relevant coding standard.
6. At a minimum, a new UDI is required whenever there is a change that could lead to misidentification of the device or ambiguity in its traceability, including recalls and other field safety correction, AE reporting, and other postmarket safety surveillance activities.
7. Reprocessors, remanufacturers, Own Brand/Private Labelers should create their own, new UDI for the reprocessed, remanufactured, or relabeled medical device, which will replace the OEM's UDI where it exists.
8. Reprocessors, remanufacturers, Private (Own Brand) Labelers shall retain record of the Original Equipment Manufacturer's (OEM) UDI.
9. The UDI contains two parts: the Device Identifier and a Production Identifier.
10. The Device Identifier (e.g., GTIN, LIC, ISBT128) should be globally unique at all levels of packaging.
11. If a lot number, serial number, or expiration date appears on the label, they should be part of the UDI Production Identifier. If there is ALSO a manufacturing date on the label, it does NOT need to be included in the PI. If there are no other PIs, the manufacturing date should be used as the PI.

7. UDI Carrier

1. The UDI Carrier (AIDC and HRI representation of the UDI) shall be on the label of the device, its package, or on the device itself, and on all higher levels of packaging.
2. The UDI Carrier for low risk devices packaged and labelled individually does not need to be on its package but rather on a higher level of packaging, e.g. carton. However, when the user is not expected to have access (e.g., home user) to the higher level of packaging (e.g., carton), the UDI should be on its package.
3. Over the Counter (OTC) devices exclusively for retail Point of Sale (POS) do not need to encode Production Identifiers in AIDC on the point of sale package.
4. No particular AIDC methods should be required by a regulatory authority. Globally accepted AIDC methods based on ISO standards that have been approved by the UDI Standards Development Organization (e.g., GS1 or HIBCC) shall be used.
5. RFID has to comply with open, commercially acceptable, industry standards such as EPC – and be vendor neutral.
6. When AIDC carriers other than the UDI Carrier are part of the product labeling, the UDI Carrier shall be readily identifiable. Carriers not intended to be part of the UDI System, but which serve other purposes, are not subject to the specific UDI requirements/standards.

7. If linear bar codes are used, the Device Identifier and the Production Identifier(s) can be concatenated or non-concatenated in two or more bar codes. All parts and elements of the UDI bar code shall be distinguishable and identifiable.
8. If there are significant constraints limiting the use of both AIDC and HRI on the label, the AIDC format shall be favored. However, certain environments or use situations, such as home care, may warrant the use of HRI over AIDC.
9. In case of RFID, a linear or 2D bar code shall also be provided.
10. Medical devices that are reusable should have a permanent UDI Carrier on the device itself.
11. Devices that require reprocessing or sterilization (except SUDs) between patient use and implants should be Direct Part Marked in addition to the UDI on the label of the device or its package. Manufacturers may determine that Direct Part Marking may not be possible or warranted on some devices due to size, design, materials, processing, or performance issues.
12. The UDI Carrier should be readable during normal use and throughout intended life of the device.
Exception – for DPM - the intended life of the UDI Carrier shall be stated in the labeling.
13. If the UDI Carrier is readily readable through the device's package, then the UDI Carrier does not also need to be on the package.
14. A single finished medical device made up of multiple parts that have to be assembled may have the permanent UDI Carrier only on one part. It should be on the device that provides the primary mode of activation.
15. The placement of the UDI Carrier should be done in a way that AIDC method can be accessed during normal operation or storage.

8. The UDI Database

All UDID data elements should be mandatory, unless marked optional. "If applicable" means the information is mandatory to be in the UDID if it is on the label. Data elements and their definitions for the UDID are listed below.

1. No product commercial confidential information shall be included in the UDID.
2. The manufacturer is responsible for the initial submission and updates to the identifying information and other device data elements in the UDID.
3. The data in the UDID should be publicly available and free of charge.
4. The presence of the device in the UDID does not mean that the device is authorized in all jurisdictions.
5. The database should allow for the linking of all the packaging levels of the product.
6. The data for new UDIs must be available before the product is put on the market.
7. Manufacturers should update the UDID within 30 days when a change is made to an attribute that does NOT require a new UDI.

8. The UDI Database shall use the HL7 Structured Product Labeling (SPL) standard for data exchange.
9. The data should be available forever; though the data could be archived if the device is no longer on the market.
10. The core elements are the minimum elements needed to identify a device through distribution and use. Regional or National UDIDs may contain additional elements; however, these additional elements should be kept to a minimum.

The core UDI Data Elements are the following:

1. For every packaging level – the following shall be provided in a related way (for entire packaging hierarchy):
 - Device Identifier (UDI type (GS1, HIBC, ISBT-128) and code)
 - Quantity per package configuration: (e.g., each, 10 eaches, 5 shelf packs)
 - Alternative or additional identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128
2. The Unit of Use Device Identifier (if applicable)
3. Manufacturer's Name
4. Manufacturer's address and contact information (as represented on the label and/or instruction for use)
5. Authorized Representatives (list of countries) (if required by the local/regional regulatory authority) Information about the regional representative's information such as the address or telephone number, when applicable. Name, Address, Email, Telephone
6. Global Medical Device Nomenclature (GMDN) Preferred code and term
7. Trade Name/Brand Name (if applicable)
8. Device model, reference, or catalogue number (if applicable)
9. How the device is controlled: serial, lot/batch number, and/or expiration date (or manufacturing date) (check boxes)
10. Clinical Size (including Volume, Length, Gauge, Diameter) (if applicable) – applicable when necessary to identify clinically relevant characteristics of the device such as measurement, size appropriate to the product (e.g. 8F catheter)
11. Additional product Description (optional) – Additional clinically relevant information, e.g., radio-opaque (free text)
12. Storage conditions, as labeled on the product and/or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight
13. Handling conditions (if different than storage conditions), as labeled on the product and/or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight
14. Labeled as single use (Yes/No)
15. Is device packaged sterile (Yes/No)
16. Does it need to be sterilized before use (Yes/No) – *if so, then the method of sterilization should be indicated [limited list to be developed] [to be validated with users]*

17. Restricted number of reuses (if applicable)
18. Labeled as containing latex (Yes/No)
19. Labeled as containing DEHP (Yes/No)
20. License and/or marketing authorization or registration number (if required by the local regulatory authority)
21. URL for additional information, e.g. electronic IFU (optional)
22. Critical warnings or contraindications (if applicable) – if a particular regulation requires that the label of the device contains a critical warning or contraindication associated with the use of the device [list to be developed].