GHWP/WG9/PD001/2025

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title:	UDI Application Guidance Considerations for Manufacture to facilitate an effective UDI Implementation
Authoring Group:	Work Group 9 – UDI and Nomenclature
Date:	August 2025

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Acknowledgements

This GHWP document was prepared by Global Harmonization Working Party (GHWP), Working Group 9 UDI and Nomenclature. We wish to acknowledge the contributions of working group members: Zhou Wenwen, Yi Li, Wang Xinbing, Cui Jun, Li Meng (Lilo Li) who contribute in preparation of the document.

To acknowledge the contributions who provide their comments

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Foreword

This GHWP Document was developed by Global Harmonization Working Party (GHWP), Working Group 9 UDI and Nomenclature. GHWP is a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and subject to consultation throughout its development process.

This GHWP Document shall be read in conjunction with the current laws and regulations used in member economies.

Any statements or references from external sources are used under appropriate citations as specified in the normative references and bibliography.

In this GHWP Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Introduction

After releasing the UDI rule, we successively released the Creation and Placement of Unique Device Identifier and UDI Data Elements. Now, in order to better promote the implementation of UDI, we have compiled this document. This document aims to promote the effective implementation of UDI and provide regulatory authorities and manufacturers with application guidelines on how to implement UDI in production.

1 Scope

This document provides an introduction and explanation regarding UDI implementation by manufacturers, and its typical application scenarios and technologies in the medical device production process. It aims to offer the necessary details and specifications to ensure more detailed guidance when implementing the GHWP UDI rule (GHWP/WG9/F001:2023). Regarding certain specific aspects mentioned in the text, national regulations may vary.

2 Normative references

The content of the following documents constitutes the essential articles of this document through normative references therein. For dated references, only the dated version applies. For undated references, the latest edition (including all amendments) applies.

ISO/IEC 15415 Automatic identification and data capture techniques - Bar code symbol print quality test specification - Two-dimensional symbols

ISO/IEC 15416 Automatic identification and data capture techniques - Bar code print quality test specification - Linear symbols

ISO/IEC 15417 Information technology—Automatic identification and data capture techniques—Code128 bar code symbology specification

IMDRF/UDI WG/N7 FINAL: 2013 UDI Guidance: Unique Device Identification (UDI) of Medical Devices

IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification system (UDI system) Application Guide

IMDRF/UDI WG/N54 FINAL: 2019 System requirement related to use of UDI in healthcare including selected use cases

3 Terms and definitions

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1 Unique Device Identifier; UDI

A series of numeric, alphanumeric and/or symbolic codes created based on the standard, including device identifier and production identifier, and used for unique identification of the medical device.

Note 1: The word "unique" does not mean serialization management for a single product.

Note 2: Can be used for the management and traceability of UDI-DI.

3.1.2 Unique device identification database; UDID

The database that stores the device identifier and other relevant information about specific devices.

3.1.3 Device identifier; UDI-DI

A unique code specific to a specification, model or packaging of medical device.

Note: Device identifier can be used as the “access key” to information stored in a unique device identification database to associate the product information, manufacturer information and registration information of the medical device.

3.1.4 Production identifier; UDI-PI

A code that identifies the data related to the production process of the medical device.

Note: According to the actual application requirements, a production identifier may include the serial number, batch/lot number, software version, manufacturing date, and expiration date of the medical device.

3.1.5 Linear bar code; one-dimensional bar code

A bar code symbol that represents information only in one-dimensional direction.

3.1.6 Two-dimensional bar code; 2D code

Two-dimensional codes are barcode symbols that represent information in two-dimensional directions.

3.1.7 Radio frequency identification; RFID

A technology that uses the electromagnetic or inductive coupling in the RF section of the spectrum to intercommunicate with an RF tag for the purpose of the unique reading of its identity through various modulation and coding schemes.

4 Essential Principles

4.1 Applicability

This document provides a general technical guidance for UDI implementation and application by medical device manufacturers. Medical device manufacturers may refer to this document when undertaking UDI implementation and its application throughout various stages, including production and sales.

4.2 Feasibility

This document is a practical summary of UDI implementation and application by relevant medical device manufacturers. By referencing this document, manufacturers can carry out quality traceability management for medical devices based on UDI, which is practically feasible.

4.3 Expandability

This document also proposes extensible UDI implementation and application for manufacturers, serving as a reference for manufacturers.
Drafted based on current regulatory requirements and technical means, this document does not restrict the adoption of new technologies or methodologies. Manufacturers may employ validated alternative approaches to comply with the requirements specified herein.

5 UDI Implementation and Application by Manufacturers

5.1 Organization and systems

5.1.1 UDI implementation and application organization

A UDI implementation and application team led by the head of an enterprise may be established. Departments such as design, production, regulatory affairs, registration, information, quality systems, finance, logistics (inventory management), and sales shall collaborate to promote UDI implementation and application, study and understand UDI-related policies, regulations, standards, coding rules and requirements of issuing agencies to provide organizational and resource support for UDI implementation and application by manufacturers.

5.1.2 Systems related to UDI implementation and application

Develop UDI implementation control procedure documents. To ensure UDI placed on the product meets application needs, manufacturers can formulate UDI implementation control procedures based on relevant policies, regulations, standards, coding rules and requirements of issuing agencies, as well as the requirements of UDI application stakeholders. These procedures shall specify departmental responsibilities, workflows, applicable product scope, selection of issuing agencies, UDI creation and placement, data carrier quality control, UDI-DI reporting, software/hardware requirements, documentation, and continuous improvement in the process of UDI coding and placement. Corresponding job responsibilities and operation specifications shall also be established.

Update production quality management working system. To ensure manufacturers apply UDI in product production quality management, UDI application can be integrated into full-process product production management according to actual needs, such as relevant system documents of R&D, production process management, inspection, sales and after-sale services, adverse event reporting and recall, and establish job responsibilities and operation specifications in compliance with UDI implementation across relevant stages.

Strengthen training on UDI-related policies, regulations, standards, and internal corporate systems.

5.2 UDI implementation quality control procedures

5.2.1 Selection of issuing agencies

Issuing agencies shall be selected by referring to the accredited and publicly available issuing agencies and coding rules specified in the UDID based on practical requirements.

5.2.2 UDI creation

The UDI includes UDI-DI and UDI-PI. UDI creation shall comply with relevant regulations and standards, ensuring that UDI-related information can be parsed at all stages, and can be accurately recorded and traced.

5.2.2.1 UDI-DI

Determine UDI-DI coding requirements in accordance with UDI regulations, standards, and coding rules of selected issuing agencies. The UDI-DI shall be stable and remain

unchanged if there are no changes in basic characteristics of medical devices. However, new UDI-DI shall be placed if there are changes that may lead to misidentification and/or unclear traceability of medical devices, such as changes in product quantity in the package, whether the package is sterile and/or whether the product is marked for single-use.

When the medical device has one or more higher packaging levels, it is recommended to assign different UDI-DI for each product packaging level of the medical device in combination with the ability of the medical device registrant and the actual product situation, and maintain association relationship in the Unique Device Identification Database (UDID). Reusable medical device should be placed with UDI data carrier by direct marking.

When defining multi-level packaging, uniqueness for the stock keeping unit (SKU) and higher-level packages shall be ensured. All supply chain parties can access required information by scanning the UDI at any packaging level without unpackaging.

If the SKU contains multiple devices that not assigned a UDI at the level of its units of use (UoU), it is recommended to assign a Unit of Use UDI-DI and establish association relationship with the SKU in the UDID.

Enterprises should create product records based on UDI-DI and associate with existing product material codes.

If applicable, enterprises recommended to map the UDI-DI to corresponding medical insurance codes in the country where the device is sold, in their own UDID.

UDI-DI information should be added to product model and specification documents to ensure the design team can reference and use DI throughout the development process.

5.2.2.2 UDI-PI

If the medical device label contains one or more of the production batch No., serial No., production date and expiration date of the medical device product, it is suggested to include them into the composition of UDI-PI, whose content shall be consistent with the corresponding information of the label. If the expression format of date is involved, the coding rules of the chosen code issuing agency shall be observed.

For medical devices controlled according to batch production, considering the application scenario, if it is necessary to identify to individual products, it is appropriate to add the serial number on the basis of the joint use of UDI-DI and production batch number, or to add other data separators according to the coding rules of the selected issuing agencies.

Enterprises shall develop product PI rules based on label information, UDI application requirements and management requirements, and provide examples in supporting documentation.

5.2.3. UDI placement

UDI placement shall comply with relevant regulations and standards. The placement shall be authentic, accurate, complete, clear, and legible.

5.2.3.1 Carrier selection

Placement shall follow the standards or specifications of the selected issuing agencies. The UDI data carrier shall satisfy such requirements as automatic identification and data capture (AIDC) and Human Readable Interpretation (HRI). In case of limited space or limited use, priority should be given to the carriers with AIDC,unless in home healthcare settings.

5.2.3.2 Carrier placement

The UDI data carrier shall be placed in a clearly visible location on the product packaging, label, or product itself. The unique identification graphical symbols specified by regulations and standards should be used to distinguish from other types of AIDC formats.

It is recommended to consider the impact of transportation, storage and handling environments on the readability of UDI data carriers.

5.2.3.3 Placement method

Manufacturer may determine the UDI placement method based on their specific circumstances. According to the type and material of the product or package or label, the placement can be completed by inkjet, thermal transfer printing, laser burning, etc.

5.2.3.4 Carrier quality testing

In order to ensure the quality of bar code symbol printing (printing), it is recommended that packaging samples be printed and sent to an institution with testing qualifications and capabilities for testing, and then start batch printing after the quality of the samples is determined, so as to achieve the purpose of controlling the quality of bar codes. Enterprises with in-house testing capabilities may perform the tests themselves.

5.2.3.5 Specific categories

For medical device kits, Software as a Medical Device (SaMD), and implantable devices, the creation and placement of UDI shall meet the requirements specific to their respective categories.

5.2.4 Software development, hardware support and verification/validation

It shall be evaluated whether the enterprise's existing software systems need to be updated and upgraded to meet the implementation needs of UDI, including the label printing software, production management software, inventory management software and other software requiring the application of UDI. If necessary, relevant software shall be updated and refined, and the software development and upgrade plans, verification processes, and outcomes shall be recorded.

It is recommended to include UDI data carrier design and printing software in the company's quality management system software inventory, perform software validation in accordance with the requirements of the enterprise's quality system software validation documents (e.g., referencing ISO 80002 and GAMP5), document the corresponding development, upgrade plans and verification processes and results. When changes occur to UDI data carrier design and printing software, it shall be evaluated to determine whether re-verification is required and continue use only after completion of verification.

It shall be confirmed whether the enterprise's existing hardware facilities meet the needs of software systems, including the tag printing equipment, and tag carrier information reading equipment, etc.

It is necessary to conduct first-order accuracy verification for UDI printing, and integrity verification for the same batch.

5.2.5 UDI records and documentation requirements

Establish corresponding work instructions in accordance with the requirements of UDI implementation control procedures.

Establish UDI-related work instruction documents during production processes in accordance with the requirements of the medical device quality management system.

Incorporate DI-related inspection criteria and items into existing inspection documentation in accordance with the requirements of the medical device quality management system.

Create and distribute UDI assignment tables for each product, and complete UDI implementation plans and records as required. Define record retention period.

5.2.6 UDI-DI Publication

For products with UDI implemented, registration documents shall include UDI-DI information, ensuring the consistency between submitted documents and data.
The medical device registrant shall upload UDI-DI and related information to the UDID before marketing, and shall be responsible for the authenticity, accuracy and integrity of the data.

5.2.7 Continuous improvement

It is recommended to conduct regular internal audits to inspect the implementation of UDI and ensure compliance with regulatory and standard requirements.
Establish effective feedback mechanisms to enable continuous improvement based on updates to UDI regulations, standards and reasonable customer needs on the basis of complying with regulations and standards.
Associate UDI with the implementation and records of corrective/preventive actions.

5.3 Design and development

During the design and development phase, it is advisable to complete the determination of the product's minimum unit of use, SKU, packaging level, UDI creation and assignment, and document in design documents. The content of UDI-PI shall be determined, and UDI-related work instructions and inspection requirements shall be established.

5.3.1 Associate UDI-DI with product documentation

For companies that have implemented digital management of UDI data and processes, the association between UDI-DI and product documentation that has been digitally managed can be established through digital means.
For companies that have not implemented digital management of UDI data and processes, it is recommended to establish association relationship between UDI-DI at the UoU level and product documentation to ensure traceability and improve convenience of document access during production.
a) Association relationship between product design drawings and UDI-DI can be established;
b) Association relationship between production work instructions and UDI-DI can be established;

5.3.2 Trial production and process validation

UDI can be created and placed to each trial production prototype (product sample submitted for inspection). The manufacturing date, batch number, or serial number information of the prototype shall be recorded.

Key parameters and operators for each production step can be recorded. The label printing procedures shall be traceable.

During process optimization, the specific parameters and effect for each optimization shall be recorded.

5.4 Production process

5.4.1 Production work order

The accuracy of production batch number/serial number, production date and other UDI-PI-related data in production work orders shall be ensured.

5.4.2 Production preparation

Based on established association between UDI-DI and product documentation, production process documents, work instructions, etc. for batch production shall be quickly and accurately retrieved.

The association relationship between UDI-related information (e.g., production batch number or serial number) and raw materials can be established if required.

5.4.3 Production process

Based on established association between UDI-DI and product documentation, relevant blank batch record documents shall be retrieved, and UDI-related information shall be reflected in relevant batch record documents to ensure record consistency and traceability. If required, direct or indirect association with UDI (or UDI-PI) information can be established in various records to enable traceability of product origins and destinations.

5.4.4 UDI placement process records and data documents

The production department shall perform product placement and establish UDI placement record documents, including label printing or placement records and label retention records according to UDI work instructions.

If applicable, relevant information system for UDI data carrier printing shall be established. If there is an independent information system for UDI placement and printing, the security and accuracy of interface data shall be ensured when exchanging

UDI-DI, product name, model and specification, production batch number, and batch quantity information with the relevant resource planning management system.
The enterprise recommended to establish its own internal UDI database containing:
(a) Basic product information, registrant/flier, and entrusted manufacturer (if applicable) information;
(b) Production information: Production date, production batch number/serial number, shelf life/expiry date, etc.;
(c) Information on UDI association relationship across product packaging levels (if any).

5.5 Inspection

5.5.1 Inspection documents

Product inspection instructions can specify the traceability of UDI during the inspection process based on actual needs. The relevant requirements are as follows:
During product quality inspection process, corresponding UDI information shall be retrievable directly or indirectly.
Where applicable, newly assigned UDI shall be retrievable and associated with the original product UDI records.
The UDI data carrier placed shall include both human-readable information and machine-readable information (e.g., one-dimensional bar code, two-dimensional bar code, or RFID), ensuring that the UDI data carrier is clearly visible and scannable at each packaging level. The UDI carrier (e.g., one-dimensional bar code, two-dimensional bar code, or RFID) shall comply with the coding rules of corresponding issuing agencies and corresponding standards and undergo required inspection or validation.
Other inspection procedures and release criteria established by the enterprise may include UDI carrier or label content based on actual needs.

5.5.2 Product production process stage

During production, process inspection shall be conducted according to UDI implementation control procedures and process inspection instructions to verify the placement and application methods of UDI data carriers on products.
Non-conforming products shall be handled according to the enterprise's non-conformity control procedures.

5.5.3 Product inspection stage

It shall be confirmed that the enterprise has completed inspections in accordance with UDI control procedures and inspection instructions.
The inspection records of UDI data carriers shall be recorded and retained.

5.5.4 Product release stage

All inspection items, including those related to UDI carriers and labels, should be completed at product release stage.
Final product release shall be conducted according to the enterprise's release requirements.

5.6 Warehousing process

5.6.1 Finished product warehousing

During the finished product warehousing process, the inbound form and products shall be inspected and verified. Based on the enterprise's actual needs, auxiliary validation may be performed by scanning relevant information, and warehousing records shall be formed, which may include:
(a) Basic product information, registrant/flier, and entrusted manufacturer (if applicable) information;
(b) Production information: Production date, production batch number/serial number, shelf life/expiry date, etc.;
(c) Direct or indirect UDI association relationship across product packaging levels (if applicable).
(d) Warehousing-related information.

5.6.2 Inventory

Inventory checks: Regular inventory checks shall be conducted to ensure consistency between physical stock with system records (if applicable). Critical information such as product storage location, product and quantity information shall be verified against system records. UDI-related information may also be verified, and inventory records shall be maintained complete and accurate.
Products exceeding expiry dates shall be placed in the non-conforming product area and subsequently destroyed according to regulations. It is recommended to record product UDI. For products with suspected quality issues identified during inspections, confirmed non-conforming items shall be moved to the non-conforming product area, and product UDI may also be recorded.

For products requiring refrigerated or frozen storage management, temperature log data may be directly/indirectly associated with UDI-related information to enhance management precision and level.

Inventory tracking and positioning: Warehouse management personnel may track and position products based on UDI information to ensure inventory accuracy.

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