GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: **GHWP UDI Rule**

Authoring Group: Working Group 9 UDI & Nomenclature

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Table of Contents

GHWP UDI Rule

Chapter I: General Provisions

The Unique Device Identification System (UDI system) is intended to provide a single, globally harmonized system to adequately identify medical devices through distribution and use. It is critical to note that the maximum benefits of a UDI system can only accrue if all stakeholders, from the manufacturer to healthcare providers and patients and Regulators, use UDI throughout their workflow systems.

Every medical device needs to be identified by a UDI, unless it is exempted. The regulatory authority of the UDI System shall specify harmonized exemptions for certain devices such as investigational devices and custom made devices from UDI requirements

A UDI system includes a Unique Device Identifier (UDI), a UDI carrier, and a UDI Database (UDID).

- The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard.

- The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI.
  Note: Carriers can include, for example, a 1D/linear bar code, a 2D/Matrix bar code, or an RFID system

- The UDID contains identifying information and other elements associated with the specific medical device.

1. The regulatory authorities that establish a UDI system are responsible for establishing a standardized UDI system to meet local regulatory requirements and to develop and maintain a local publicly available UDID that is capable of linking, to the extent possible, to other regulatory authority UDIDs. It is recognized that local specificities and regulations could impact certain aspects of UDI implementation.

   Manufacturers are responsible for understanding both regulatory and issuing

agency/entity requirements or standards to accurately assign and place the UDI in human readable and AIDC format on the label or on the device itself and on all higher levels of device packaging, as appropriate. Manufacturers are also responsible for the initial submission of, and updates to, the information in the UDID.

It is recommended that all stakeholders related to UDI actively use it throughout their workflow systems.

Chapter II: UDI

2. The UDI contains two parts: device identifier (UDI-DI) and production identifier (UDI-PI).

The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID.

The UDI-PI 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, Software as a Medical Device (SaMD) version, manufacturing date or expiration date.

A new UDI-DI is required whenever there is a change that could lead to misidentification of the medical device and/or ambiguity in its traceability. Any change of one of the following UDID data elements determines the need for a new UDI-DI:

a.Brand Name,
b.Device version or model,
c.Clinical Size (including Volume, Length, Gauge, Diameter),
d.Labeled as single use,
e.Packaged sterile,
f.Need for sterilization before use,
g.Quantity of devices provided in a package,
h.Critical warnings or contraindications: e.g. containing latex or DEHP.

A UDI-DI allocated to a particular medical device should never be reused. Devices that have been withdrawn from the market and are reintroduced may use the

original UDI-DI if they are reintroduced without any modifications or changes which require a new UDI-DI.

3. Manufacturers are responsible for following both regulatory and issuing agency/entity requirements or standards to accurately assign the UDI at the packaging level of the device so that it can be adequately identified through its distribution.

The UoU DI is an unmarked identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to provide a UDI-DI to identify a device used on a patient when a UDI-DI does not appear on the label of the device.

4. An Issuing Agency/Entity is an organization accredited by a regulatory authority to operate a system for the issuance of UDIs. An Issuing Agency/Entity shall meet the following criteria：

(a) its system for the assignment of UDIs is adequate to identify a device throughout its distribution and use in accordance with the requirements of the regulatory authority and conforms to the relevant international standards;
(b) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a single set of consistent, fair and reasonable terms and conditions;
(c) it makes available to the regulatory authority, upon request, information concerning its system for the assignment of UDIs; and
(d) it meets the relevant requirements for data security of the local regulatory authority.

Chapter III: UDI Carrier

5. A UDI Carrier includes both AIDC and HRI formats. If there are significant constraints limiting the use of both on the label, the AIDC format shall be favored. No particular AIDC methods should be required by a regulatory authority. The HRI format shall follow the rules of the UDI code issuing organization.

Commonly used AIDC technologies in the medical device industry include 1D/linear bar codes, 2D/Matrix bar codes, and RFID. If linear bar codes are used, the UDI-DI and UDI-PI can be concatenated or non-concatenated. Where RFID is used, a linear or 2D bar code shall also be provided on the label.

6. The manufacturer is responsible for placing the UDI Carrier on the label or on the device itself, and on all higher levels of device packaging, not including shipping containers. The UDI Carrier should be readable during normal use and throughout intended life of the medical device.

Chapter IV: UDID

7. Regulatory authorities are responsible for developing the UDID in their jurisdiction based upon local policy requirements. However, locally specific data elements should be avoided. The UDID should follow a globally harmonized approach so that healthcare professionals and patients will have access to a single consistent, and complete source of information about a medical device and its key attributes. The UDID shall be accessible to the public free of charge.

8. The manufacturer is responsible for the initial submission of identifying information and other medical device data elements in the UDID.

   Manufacturers should update the relevant UDID record in a timely manner when a change is made to an element that does not require a new UDI-DI.

Chapter V: Supplementary Provisions

9. The use of a UDI System will facilitate and simplify the documentation of medical device use in various patient records including traditional as well as electronic health records and registries. A UDI system should also enable linkages of medical device information across various systems and across geographies. These applications of UDI could help to identify medical device problems and enhance data analysis.

   The global use of a UDI will facilitate traceability throughout distribution. In order to achieve traceability, it is necessary to involve all stakeholders in the capture and recording of the UDI (UDI-DI + UDI-PI) throughout distribution and use.

10. The definition of the following terms in this rule:
    Automatic Identification and Data Capture (AIDC)
    A technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Human Readable Interpretation (HRI)

Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier.

Shipping containers

Shipping container is a container where the traceability is controlled by a process specific to logistics systems.

11. A risk-based approach is essential to facilitate an effective implementation of UDI system. Implementation should be phased in over a period of years based on product risk classes, starting with the highest risk class, to reduce the burden of implementation.

References

IMDRF/UDI WG/N7Final: 2013 - UDI Guidance: Unique Device Identification (UDI) of Medical Devices

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

US, EU, and China, UDI rule

Abbreviations

Automatic Identification and Data Capture (AIDC)
Device Identifier (UDI-DI)
Human Readable Interpretation (HRI)
Production Identifier (UDI-PI)
Software as a Medical Device (SaMD)
Unique Device Identification system (UDI system)
Unique Device Identifier (UDI)
Unit of Use (UoU)

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