UDI in the MDR

The European Union intends to replace the existing directives related to medical device, Active Implantable Medical Devices, In Vitro Diagnostic Devices, and Medical Devices, with two regulations. The regulations include a number of changes and new requirements beyond the existing directives. The process starts with publication in the Official Journal, anticipated by the end of 2016, with a three-year transition for the Medical Device Regulation (MDR) and a five-year transition for In Vitro Diagnostic Regulation (IVDR).

One of the major changes is the creation of an EU system for Unique Device Identification, UDI. Both the MDR and the IVDR require UDI. The information published to date shows that the regulations have almost identical requirements. However, the clause numbers differ significantly, so this paper describes the MDR only.

In addition to the "simple" requirements to put a UDI on the label and load a database there are other requirements that extend the system.

Economic Operators
The new regulations create Economic Operators who play a role in the UDI system.

In both regulations, an economic operator means the manufacturer, the authorized representative, the importer, and the distributor. In the MDR, economic operator also includes:

An organization that assembles systems or procedure packs
An organization that sterilizes systems or procedure packs

Both regulations include a definition for each type of economic operator. These definitions don't agree with the definitions in EN ISO 13485:2016. In the EU, the regulations take precedence.

Before placing a device on the market any manufacturer, authorized representative, and importer must register in the European Databank. The Competent Authority obtains a single registration number (SRN) and provides it to the manufacturer, authorized representative, or importer. The manufacturer uses the single registration number when applying to a Notified Body for certification. The manufacturer uses the single registration number to enter information in the UDI electronic system.

<u>Manufacturer</u>
The responsibilities of the manufacturer for UDI include:

- Comply with the obligations related to the UDI system
- Control the UDI-Code assignments through the QMS
    - EN ISO 13485:2016 includes UDI requirements in Clause 7.5.8 Identification
- Draw up and maintain technical documentation; see Annex II
    - Include the Basic UDI device identifier attributed by the manufacturer to the device
- Draw up an EU Declaration of Conformity; see Article 17
    - Include the required information from Annex III including the basic UDI-DI
- Supply the accompanying information; see Annex I Section 19
    - Ensure the label has the UDI carrier

- Have a system for recording and reporting of incidents and field safety corrective actions as described in Article 61
    - Article 64(4c) requires the UDI in the reports

Authorized Representative

The responsibilities of the authorized representative for UDI include:

- Where the manufacturer of a device is not established in any Member State, the device may only be placed on the Union market if the manufacturer designates a single authorized representative.
- The authorized representative:
    - Verifies the manufacturer's EU declaration of conformity, technical documentation, and conformity assessment procedure has been carried out by the manufacturer;
    - Keeps a copy of the manufacturer's EU declaration of conformity, technical documentation, and Notified Body certificates (including any amendments and supplements)
    - Registers as an authorized representative
    - Verifies that the manufacturer has registered

Importer

The responsibilities of the importer for UDI include:

- To place a device on the market, the importer verifies:
    - The device has a CE Mark and a Declaration of Conformity
    - The manufacturer is identified
    - The authorized representative is designated by the manufacturer
    - The device is labelled and has the required instructions for use
    - The manufacturer has assigned the Unique Device Identification
- Keeps a copy of the manufacturer's EU declaration of conformity and Notified Body certificates (including any amendments and supplements)
- Importers add their name, registered trade name or registered trademark, and the address of their registered place of business to the device, packaging, or documentation.

Distributor

The responsibilities of the distributor for UDI include:

- To place a device on the market, the distributor verifies:
    - The device has a CE Mark and a Declaration of Conformity
    - The device has the information required by Annex I Section 19 for the label and instructions for use in an official Union language determined by the Member State where the device is made available to the user or patient.
    - For imported devices, the importer has identified themselves
    - The manufacturer has assigned the Unique Device Identification

Definitions

Unique Device Identification (UDI) – 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 device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

Device Identifier (UDI-DI) – The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the "access key" to information stored in a UDI database.

Production Identifier (UDI-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, software identification, and/or manufacturing and/or expiration date.

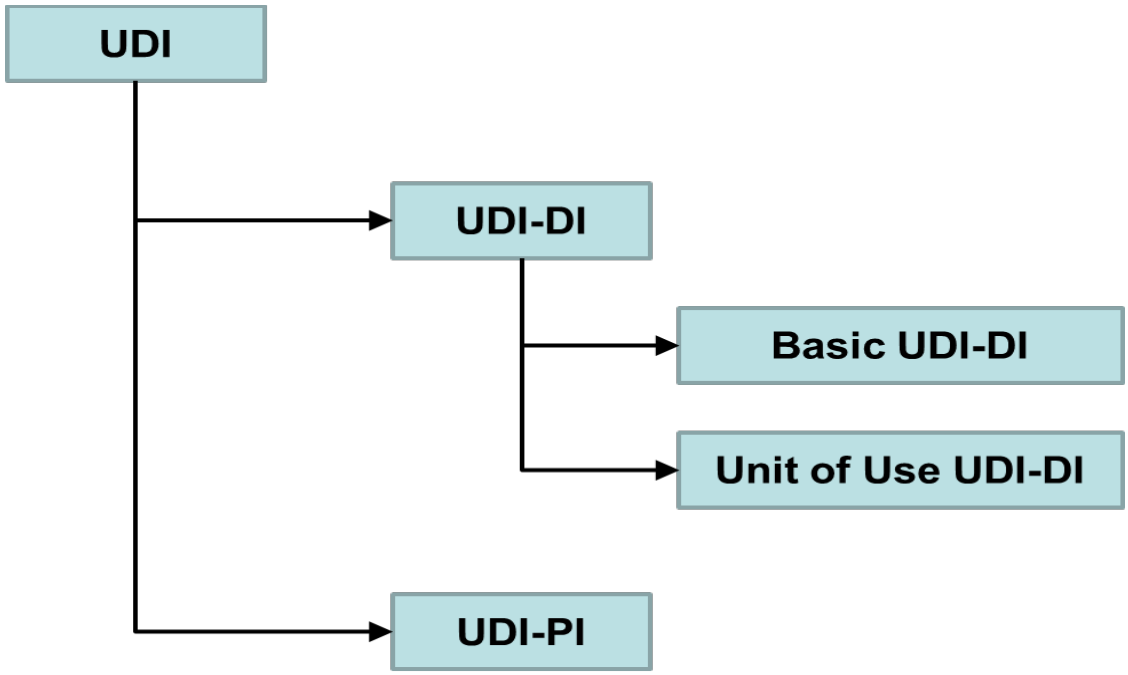

Figure 1 UDI Structure

The UDI on the label uses AIDC as defined below. The AIDC includes a carrier with the data and a Human Readable Interface.

Automatic Identification and Data Capture (AIDC) – AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics, and RFID.

UDI Carrier – The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI.

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

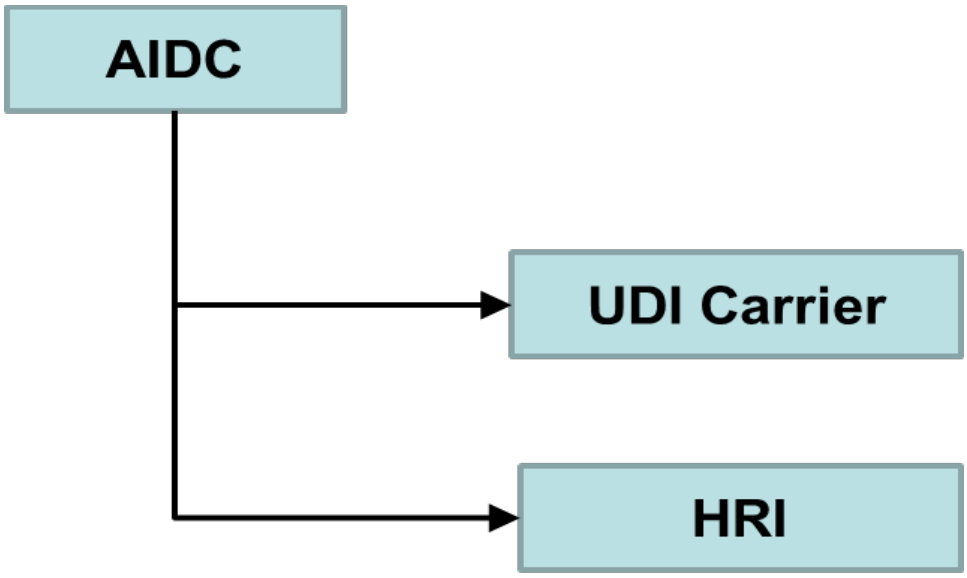

Figure 2 AIDC Structure

The UDI System

The Commission will designate entities to operate a UDI assignment system. To qualify, a designated entity must be a legal organization with an adequate UDI assignment system that conforms with international standards. The entity must agree to transparent terms and condition and remain in business for at least 10 years.

Before placing a device on the market, the manufacturer assigns a UDI to the device and the higher packaging levels. The device label and the higher packaging levels carry the AIDC.

The Declaration of Conformity includes the basic UDI-DI. The technical documentation includes an up-to-date list of all applied UDIs.

The manufacturer uses the UDI in reporting serious incidents and field safety corrective actions.

The manufacturer assigns a new UDI-DI whenever a change could lead to misidentification of the device or when any of the following characteristics change:

(a) Brand Name or Trade name
(b) Device version or model
(d) Labelled 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

The UDI Database
The Commission will establish and maintain a UDI database, to validate, collate, process, and make available to the public the UDI information. The core data elements in the UDI database shall be accessible to the public free of charge.

The regulations include the UDI-DI and about 23 other data items.