NEW EU Regulations and the EU UDI system

24 October 2017, Brussels

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GS1 & UDI
GS1: global system of standards to ensure visibility

Identify: GS1 Standards for Identification

GS1 Barcodes

EAN/UPC
GS1-128
ITF-14
GS1 DataBar
GS1 DataMatrix
GS1 QR Code
GS1 Composite Barcode
EPC HF Gen 2
EPC UHF Gen 2

Capture: GS1 Standards for Barcodes & EPC/RFID

Share: GS1 Standards for Data Exchange

Master Data Global Data Synchronisation Network (GDSN)
Transactional Data eCom (EDI)
Event Data EPC Information Services (EPCIS)

Interoperability

Item Master Data
Location Data
Item/Shipmen Tracking
Traceability
Product Recall/Withdrawal
Pedigree
Purchase Order/Despatch Advice/Invoice

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UDI system at a glance

UDI
• DI (Static Data)
• PI (Dynamic Data)

UDID
Static Data Elements
• DI = Primary Access Key

AIDC
Machine Readable Data Carrier
• Linear Barcode
• GS1 DataMatrix
• RFID

Unique Device Identification
Unique Device Identification Database
Automatic Identification and Data Capture
UDI system and GS1 system

UDI system as defined by IMDRF

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Unique Device Identification

Identify

Unique Device Identification Database

Share

Automatic Identification and Data Capture

Capture

GS1 system
GS1 key to implement requirements on medical devices

- Accredited as UDI Issuing Agency by the US FDA
- 99% of medical devices identified with GTIN in Japan
  MHLW Annual Survey, 2012
- UDI assigning entities listed in the EU MDR
- Mandated by ANMAT for traceability of certain devices in Argentina
- £3 million on average saved each year in every NHS hospital in England
  Lord Carter interim report, 2015
- 91.8% of devices identified with GTIN in Turkey
  Turkish National Drug and Medical Device Databank (TITUBB)
UDI in Europe
Device identification system: a UDI system is established

Scope:
- Apply to all medical devices placed on the market except custom-made devices

Approach:
- Substantially based on internationally recognised principles and guidance

Use of UDI:
- Basic UDI-DI is the access key for device-related information entered in EUDAMED
- Reference to Basic UDI-DI in key documentation (Declaration of conformity, certificates)
- UDI shall be used for reporting serious incidents and field safety corrective actions
- UDI storage obligations for Class III implantable devices

Source: European Commission, April 2017

EU - UDI: the EU roadmap
(provided that EUDAMED is functional)

- **2012** EC proposals MD & IVD Regulations
- **2013** EC Recommendation to MS
- **5 May 2017** EU Regulations published

**Development of EUDAMED**

- **26 May 2020** UDI assignment, registration and EUDAMED
- **2021** UDI marking Class III
- **2022** UDI marking Class II
- **2025** UDI marking Class I

- **26 May 2022** UDI assignment, registration and EUDAMED
- **2023** UDI marking Class D
- **2025** UDI marking Class B & C
- **2027** UDI marking Class A

+ 2 years for DPM, when applicable
UDI system in EU

• Assignment of a UDI made of a DI and a PI

• Application of the UDI on the label or the package of the device. The UDI carrier shall be placed on the label and on all higher levels of packaging (not incl. shipping containers)

• Storage of the UDI by the economic operators, the health institutions and the healthcare professionals

• Data submission in a UDI database (EUDAMED)
Storage and traceability requirements in the EU

Storage:

• store and keep, *preferably by electronic means*, the UDI for class 3 implantable devices and for devices identified via implementing acts
• Only class 3 implantable devices for health institutions

Traceability:

• identify any operators/health institution to whom have directly supplied a device and any operator who has directly supplied them with a device: one-up-one-down traceability model
• The UDI shall be included in the field safety notice for reporting serious incidents and field safety corrective actions.
The EU Commission definition of “Basic UDI-DI”:

“The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and shall be referenced in relevant certificates and declarations of conformity.”

(MDR as officially adopted, before publication – Annex VI Part C. 1)
EU “Basic UDI-DI”

Before or after the supply chain, where Basic UDI-DI is needed

In the supply chain, where trade item ID (GTIN) is to order, deliver, or invoice

GTINs

Level | QTY | DI | QTY | DI | QTY | DI
---|---|---|---|---|---|---
UoU UDI-DI | 1 | GTIN A | 10 | GTIN D | 1 | GTIN H
Base Pack | 50 | GTIN B | 20 | GTIN I
2nd | 250 | GTIN C | Package DI
3rd | | | | Base Package DI

UDI Unit of Use
CE Mark, FR, DE, EN
US Only
EN, ES

LABEL CONFIG.
Where the “Basic UDI-DI” will be used?

"Basic UDI-DI" is the main key linking device data across Eudamed

Part that the U.S. FDA UDI system focuses on today...
EU “Basic UDI-DI”

- Not a supply chain identifier (used for registration, certification, UDI, market surveillance, clinical investigation)
- Is not required on the label
- Uniquely identifies a device “model”:
  - regardless of packaging level
  - regardless of variations in minor characteristics
- Serves as the main identifier to access the EU Database on medical devices (i.e. EUDAMED)
- Links all UDI-DIs (a.k.a. GTIN’s) related to a single device: additional DI, Packaging DIs, etc.
- References the device in documents stating its compliance
EU vs US similarities (non-exhaustive list)

- Based on and aligned with the IMDRF UDI guidance
- Three issuing entities/agencies: GS1, HIBCC, ICCBBA
- Logistic items are exempted
- PIs (generally) not specified
- Retail/POS do not require PIs in UDI
- Reusable devices need a direct mark UDI
- UDI for implants must be identifiable prior to implantation
- UDI Database contains static core data attributes for each device
- Data for a new UDI-DI must be entered before the device is placed on the market; other changes within 30 days
- New UDI-DI is required when there is a change to the device or in certain UDI Database fields
- Barcode verification
EU vs US differences  *(non-exhaustive list)*

- **UDI Responsible**: Legal Manufacturer in the EU (Labeler in the US)
- Classification of devices is different
- Single Use Devices packaging exception: limited to class I/Iia, class A/B in the EU (not limited to any class in the U.S.)
- Procedure packs (i.e. “kits”) and systems: in the EU individual devices must be UDI compliant – unless Single Use Devices or already exempted- (exempted in the US)
- Standardized date format (YYYY-MM-DD): not defined in the EU
- Software: UDI on the label and software must be identical in the EU
- Class I devices: both DI and PI in the EU (DI is sufficient the US)
- Direct Marking: UDI must be both AIDC and HRI in the EU
- Active implants: serial number is required
EU vs US differences  (non-exhaustive list)

- In the EU, in cases of significant space constraints, the barcode format (not the HRI) shall be favoured unless the device is intended to be used outside of health institutions (e.g. devices used for home care).
- Exemptions are different in the EU in the US
EUDAMED

• Manufacturers can upload the data into EUDAMED via web-portal (manually) or XML (machine-to-machine)
• Divided into economic operators registration, product registration and UDI registration
• Delegated/implementing acts to provide more details on implementation

• **Deadline** for implementation should cover all class of MD

• **Open points** :
  - deadline for EUDAMED to be operational?
  - HL7/SPL acceptance? need to design the XML structure?
  - Nomenclature to be used?
UDI in the rest of the world:
get ready!
The need to align on a global UDI framework

- It is crucial that regulators around the world align on the IMDRF Guidelines and ensure consistency when setting-up regional or national UDI system.

- This would ensure:
  - highest levels of patient safety beyond borders
  - harmonized identification systems for medical devices globally
  - allow for consistency in UDI Databases across countries
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