Overview of elements or building blocks of UDI and IMDRF Documents- IMDRF/UDI WG/N48 and N53

Erin Cutts

International Affairs Policy Analyst

Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration

Orla Daly

Policy Officer

Medical Devices and Health Technology Assessment Unit

European Commission

Nada Alkhayat

Policy Officer

Medical Devices and Health Technology Assessment Unit

European Commission

Building blocks of UDI

The IMDRF guidance and procedural documents:

IMDRF/UDI WG/N7FINAL:2013	UDI Guidance: Unique Device Identification (UDI) of Medical Devices - PDF (324kb) UDI Guidance: Unique Device Identification (UDI) of Medical Devices - DOCX (130kb)	18 December 2013
IMDRF/UDI WG/N48FINAL:2019	Unique Device Identification system (UDI system) Application Guide - PDF (3.53Mb) Unique Device Identification system (UDI system) Application Guide - DOCX (12.5Mb)	21 March 2019
IMDRF/UDI WG/N54FINAL:2019	System requirements related to use of UDI in healthcare including selected use cases - PDF (306kb) System requirements related to use of UDI in healthcare including selected use cases - DOCX (10.1Mb)	21 March 2019
IMDRF/UDI WG/N53FINAL:2019	Use of UDI Data Elements across different IMDRF Jurisdictions - PDF (86kb) Use of UDI Data Elements across different IMDRF Jurisdictions - DOC (71kb) Annex - Use of UDI Data Elements across different IMDRF Jurisdictions - XLSX (391kb)	21 March 2019

IMDRF/UDI WG/N48 is an **Application Guide** intended to provide the details and **specifications** necessary to **ensure consistency** for enabling a harmonized approach in the **application** of the requirements set forth in the IMDRF UDI Guidance **N7** Document.

IMDRF International Medical Device Regulators Forum

Final Document

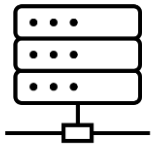
Title:	**Unique Device Identification system (UDI system) Application Guide**
Authoring Group:	IMDRF UDI WG
Date:	21 March 2019

Elena M. Astapenko, IMDRF Chair

UDI System: Fundamental elements

A Harmonized UDI System

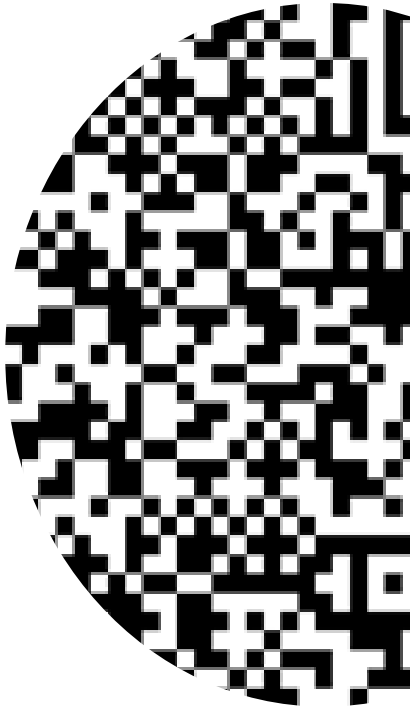
- ✓ Development of a standardized system of Unique Device Identifiers (UDIs);
- ✓ Placement of UDIs in human readable (HRI) and AIDC formats on package labels and in some cases, on the device itself;



- ✓ Submission of core UDI data elements to a database;
- ✓ Setting of appropriate transitional and implementation arrangements to ensure a smooth UDI system implementation.

- ✓ Benefits of the UDI system strongly rely on effective integration of the UDI system to support various regulatory activities during the lifecycle of medical devices and uptake of the UDI system across the whole healthcare sector.
- ✓ Issuing Entities/Agencies : e.g. GS1, ICCBBA, HIBCC

UDI System: Fundamental elements



The Unique Device Identifier (UDI)

- The UDI is composed of two parts:

Unique Device Identifier **(UDI) =** Device Identifier **(UDI-DI) +** Production Identifier **(UDI-PI)**

The UDI carrier

- The UDI Carrier shall be on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers. This can be done through labels or direct marking.
- N48 also gives guidance on how to place a UDI carrier on the label of the device or on the device itself, gives indications on direct marking

Formats

- Human Readable Interpretation (HRI) Format
- Automatic Identification Data Capture (AIDC) representation of UDI

Unique Device Identification Database & considerations on special cases

The Unique Device Identification Database (UDID)

- Covers the different roles and responsibilities of actors such as the regulatory authorities, the manufacturers (including OBLs), the issuing agencies/entities, distributors and importers, healthcare providers and retail pharmacies , and other stakeholders.
- The guidance also elaborates on expectations for an effective database design, data specifications, UDI-DI triggers, etc.

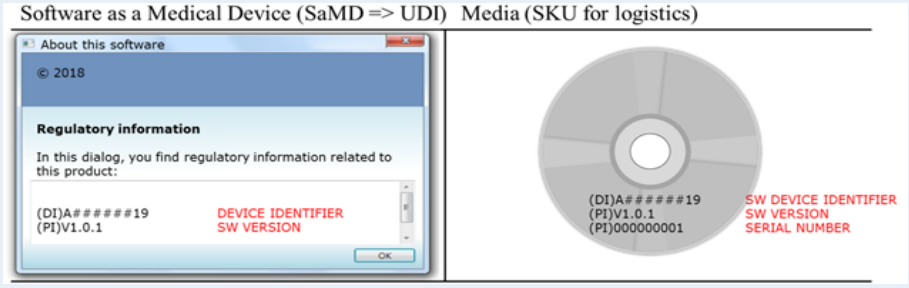
Special cases

- N48, complements or, where necessary, clarifies some of the requirements set in Section 10 of the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013).
- Provides particular considerations for implantable devices, reusable devices, non-IVD.
- Clarifies the application of UDI-DI/PI for IVD kits in terms of identifying the contents and placement of the UDI.
- Elaborates on UDI assignment and placement criteria for certain products (configurable medical devices, Software as a Medical Device, etc.)

N48 Appendices A-E

Appendices	Content
Appendix A: UDI HRI formats to be used for each of the issuing agencies/entities	Describes the GS1, HIBCC, ICCBBA Standards, specifying the qualifiers, identifiers, data types, the human readable and database field size. Provides examples of the Human Readable barcodes
Appendix B: AIDC carriers most widely used in healthcare	Visuals of GS1, HIBCC, ICCBBA data matrices, and concatenated/non-concatenated barcodes  
Appendix C: RFID carriers	Provides examples how data encoded in barcodes can also be encoded in Radio-frequency identification (RFID) tags. 
Appendix D: Registration of packaging configurations	Provides examples of how package Dis can be assigned and how configurations of a device are part of the same UDI-DI record in the UDID.
Appendix E: UoU and packaging configurations	Provides examples of how single unmarked items can be packaged in trays/boxes/cases of e.g. 25/50/75 and how UDI is assigned to those levels. 

N48 Appendices F-I

Appendices	Content
Appendix F: Direct marking integrity	Details feasibility issues linked to surface wear/treatment, scratches, abrasions, corrosion, choice of material may contribute to loss of readability. Considerations on laser marking to maintain readability.  
Appendix G: Kits	Provides examples and recommended best practices for IVD and non-IVD kits.
Appendix H: Configurable medical devices	Sets out examples of changes to configurable medical devices, differentiating between those changes that makes it necessary to identify the changed devices and those where the UDI remains unchanged.
Appendix I: Software	Example of UDI assignment for software on different media and reporting to UDID. 

IMDRF/UDI WG/N53 provides a UDI data elements dictionary containing descriptions of the data elements as collected in National UDI databases (UDID) across jurisdictions.

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Use of UDI Data Elements across different IMDRF Jurisdictions

Authoring Group: IMDRF UDI WG

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

As with IMDRF/UDI WG/N48, IMDRF/UDI WG/N53 is intended for all relevant stakeholders within the healthcare supply chain and clinical care systems.

- The data dictionary:
  - provides the reader with a better understanding of their role and impact on the UDI system;
  - is easily accessible to users and managers of data systems;
  - translates data elements into real-world terms; and
  - helps users submit data to the database.

IMDRF/UDI WG/N53 includes document as well as spreadsheet annex.

- Spreadsheet annex includes
  - “Notes” sheet to orient reader and provide definitions
  - “IMDRF-2013 UDID CDE” sheet with list of data elements recommended by IMDRF UDI Guide (N7)
  - “Comparison-Data Elements” sheet with a side-by-side view of data element names and database requirements by the IMDRF UDI guide and the participating jurisdictions

“Notes” sheet orients reader to the spreadsheet and provides definitions.

R	The data element is **REQUIRED** for submissions to that UDI database.
C	The data element is **CONDITIONALLY REQUIRED** for submissions to that UDI database. See the individual tab for that UDI database for a conditions under which this element must be provided.
O	The data element is **OPTIONAL** for submissions to that UDI database.
A	The data element is **AUTO-POPULATED** in the UDI database based on another attribute which has been provided.
--	The data element is not recognized by that UDI database and should not be included in submissions.
	A red highlighted cell indicates that changes to this data element are not allowed; a ***new Device Identifier is required*** .

“IMDRF-2013 UDID CDE” sheet lists data elements recommended by IMDRF UDI Guide (IMDRF/UDI WG/N7)

Source	Data Element	Description	Required in Database ?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger
IMDRF	UDI Type	Globally accepted ISO/IEC coding standards implemented 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; proliferation of coding systems must be	Required			
IMDRF	UDI-DI	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. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeler Identification Code), ISBT 128-PPIC (Processor Product Identification Code).	Required			
IMDRF	Quantity per Package		Required			yes

“Comparison-Data Elements” sheet with a side-by-side view of data element names and database requirements by the IMDRF UDI guide and the participating jurisdictions.

Jurisdiction	IMDRF			European Union		United States	
Source	IMDRF/UDI WG/N7FINAL:2013 Section 9.2			http://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en		https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm	
Date revised				18-Feb-2019		18-Feb-2019	
	Data Element #	Data Element	UDID Requirement	Data Element	EUDAMED Requirement	Data Element	GUDID Requirement
Device Identification & Description	--	--	--	Basic UDI-DI	R	--	--
	1	UDI-DI (UDI type, e.g. GS1 GTIN, HIBC-LIC, ISBT-128 PPIC)	R	UDI-DI	R	Primary DI Number	R
				Issuing Entity (UDI-DI)	R	Issuing Agency	R
				Isuing Entity (Basic UDI-DI)	R	--	--
	--	--	--	Single Registration Number	R	--	--
	9	Brand Name	C	Name or Trade name (name of product)	R	Brand Name	R
	11	Device model or version	R	Name or, if applicable, device model that identifies the BASIC UDI-DI Group in the technical documentation and/or certificate and declaration of conformity	R	Version or Model	R
	12	Reference and/or catalogue number	C	Reference, article or catalogue number	R	Catalog Number	O
	15	Additional product Description (optional) – Additional clinically relevant information, e.g. radio-opaque	O	Additional product Description	O	Device Description	O
	--	--	--	Direct Marking (DM) DI	R	DM DI Different from Primary DI	C
	--	--	--	--	--	DM DI Number	C
	--	--	--	Issuing Entity (Secondary DI)	C	Issuing Agency (Secondary DI)	O
	1	Additional device identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128	C	Secondary UDI-DI	C	Secondary DI Number	O

Thank you for your attention.
Now we'll turn back to the moderator for our Q&A session for Part 1 of the workshop.