Vision of a Global Unique Device Identifier (UDI) System

European Commission and US FDA

Solving a global problem requires a global solution - Key Drivers for a global UDI system

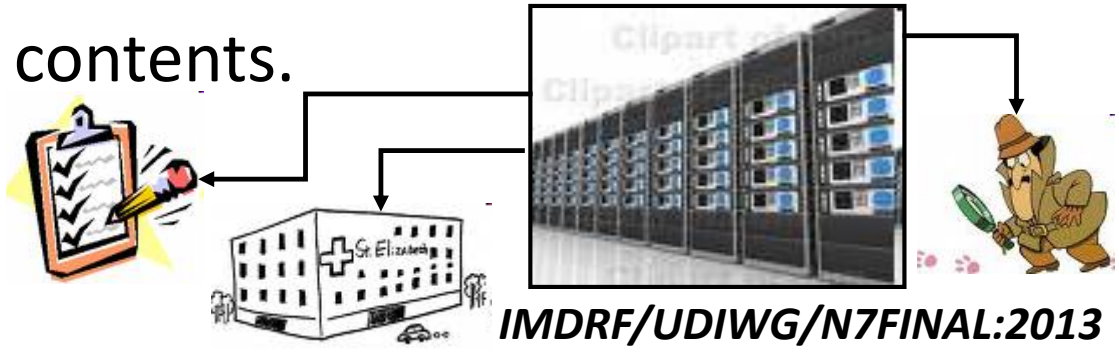
- Patient safety and supply chain management and traceability were identified by regulators as high priority in the rapidly developing healthcare sector.
- The sector of medical devices covers around 500,000 different types of medical devices on the global market. Traceability is a key problem resulting in proliferation of counterfeit devices, inadequate device recalls and insufficient field safety corrections or adverse event reporting.
- IMDRF regulators commonly agreed that a harmonised global identification principles and system were necessary to unambiguously identify medical devices in the global healthcare supply chain.

What is the Unique Device Identification (UDI) system?

- The UDI System is intended to provide a single, globally harmonised system for positive identification of medical devices. Healthcare professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a medical device and, its key attributes.

The UDI System is essential based on three key pillars:

1) UDI production,
2) UDI application on the label or on the device,
3) UDI Database (UDID) fundamental contents.



IMDRF/UDIWG/N7FINAL:2013

Benefits of the UDI system

A globally harmonized and consistent approach to UDI is expected to increase patient safety and help optimize patient care by facilitating :

- Secure global supply and distribution chain to prevent counterfeiting of medical devices
- Effective management of post-market safety-related activities, such as adverse event reporting, medical device recalls, etc.
- Cumulative information related to medical devices to reduce medical errors by healthcare professionals
- Uniform documentation for robust pre-market assessment of medical devices for the healthcare industry and public

IMDRF/UDIWG/N7FINAL:2013

These benefits can only be reaped with:

- Effective integration of the UDI to support international regulatory activities during the lifecycle of the medical device,
- Harmonization of UDI core elements across jurisdictions, and
- Uptake of UDI across the whole healthcare sector.

- Benefits are more likely be achieved when the UDI is recorded in real world electronic health systems (e.g. electronic health records (EHRs), device registries, material management systems, and reimbursement data) and used as part of real world evidence to improve clinical and regulatory decision making.

The fundamental concepts of a global UDI system include

- the UDI and UDI Carrier are based on standards,
- a UDI applied to a medical device anywhere in the world should be able to be used globally and to meet the UDI requirements of its regulatory authority,
- national or local identification numbers should NOT be a substitute for UDI,
- regulatory authorities should not specify the procedure for modifying these UDI standards
- the UDID core elements (e.g., GMDN preferred code/term) should not be modified,
- the UDID should use the Health Level Seven International (HL7) Structured Product Label (SPL) and web based interface for data submission,
- every medical device needs to be identified by a UDI, unless it is exempted

Much work within GHTF and then IMDRF has been done to provide guidance on a global UDI system.

- IMDRF/UDI WG/N7 (2013): “UDI Guidance”
  - Provides framework for regulatory authorities that intend to develop their UDI systems in a globally harmonized approach.
- IMDRF/UDI WG/N48 (2019): “Unique Device Identification system (UDI system) Application Guide”
  - Provides details and specifications necessary to ensure consistency for enabling a harmonized approach in the application of the requirements of IMDRF/UDI WG/N7.
- IMDRF/UDI WG/N53 (2019): “Use of UDI Data Elements across different IMDRF Jurisdictions”
  - Provides a UDI data elements dictionary containing descriptions of the data elements as collected in National UDI databases (UDID) across jurisdictions.
- IMDRF/UDI WG/N54 (2019): “System requirements related to use of UDI in healthcare including selected use cases”
  - Provides some general system requirements related to use of UDI in healthcare including selected use cases demonstrating how recording UDI combined with pulling data from UDID is used to auto-populate information into forms/electronic information.

- Today we will be talking about IMDRF/UDI WG/N48 and IMDRF/UDI WG/N53 in Part 1 of this workshop. We will also have the opportunity to hear from other stakeholders including regulators, industry, and healthcare providers on where we are relative to a global UDI system.

US has been progressing towards a UDI system for several years.

US Implementation Timeline

	Date	Must bear a UDI and Submit data to GUDID	Direct Marking (for certain intended uses)
✓	**Sep 24, 2014**	**Class III devices** Devices licensed under the PHS Act	
✓	**Sep 24, 2015**	Implantable, life-supporting and life-sustaining (I/LS/LS) devices	LS/LS devices
✓	**Sep 24, 2016**	**Class II devices** (not I/LS/LS)	Class III devices and devices licensed under the PHS Act
✓	**Sep 24, 2018**	Class I devices Unclassified devices (not I/LS/LS)	Class II devices (not LS/LS)
✓	**Sep 24, 2020**	**Class I devices** Unclassified devices (not I/LS/LS)	Class I devices Unclassified devices (not LS/LS)
	Sep 24, 2022	**Class I devices** **Unclassified devices** **(not I/LS/LS)**	**Class I devices** **Unclassified devices** **(not LS/LS)**

2018 Guidance

2020 Guidance

2018 Guidance

EU Implementation timelines

Device as per Regulation (EU) 2017/745 (MDR)	Implantable devices and Class III devices	Class IIa and Class IIb devices	Class I devices
Placing UDI-carriers on the labels of devices MDR Article 123(3)(f), Article 27(4)	26 May 2021	26 May 2023	26 May 2025
Direct marking of the reusable devices MDR Article 123(3)(g), Article 27(4)	26 May 2023	26 May 2025	26 May 2027

Device as per Regulation (EU) 2017/746 (IVDR)	Class D IVDs	Class C and B IVDs	Class A IVDs
Placing UDI-carriers on the labels of devices IVDR Article 113(3)(e), Article 24(4)	26 May 2023	26 May 2025	26 May 2027

EU UDI supportive guidance for industry

Reference	Title	Publication
MDCG 2021-19Search for available translations of the preceding link	Guidance note integration of the UDI within an organisation's quality management system	July 2021
MDCG 2021-10Search for available translations of the preceding link	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices	June 2021
MDCG 2021-09Search for available translations of the preceding link	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers	May 2021
MDCG 2018-1 Rev. 4Search for available translations of the preceding link	Guidance on basic UDI-DI and changes to UDI-DI	April 2021
MDCG 2020-18Search for available translations of the preceding link	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers	December 2020
MDCG 2019-2Search for available translations of the preceding link	Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017	February 2019
MDCG 2019-1Search for available translations of the preceding link	MDCG guiding principles for issuing entities rules on basic UDI-DI	January 2019
MDCG 2018-7Search for available translations of the preceding link	Provisional considerations regarding language issues associated with the UDI database	October 2018
MDCG 2018-6Search for available translations of the preceding link	Clarifications of UDI related responsibilities in relation to article 16	October 2018
MDCG 2018-5Search for available translations of the preceding link	UDI assignment to medical device software	October 2018
MDCG 2018-4Search for available translations of the preceding link	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs	October 2018
MDCG 2018-3 Rev.1Search for available translations of the preceding link	Guidance on UDI for systems and procedure packs	June 2020
MDCG 2018-2Search for available translations of the preceding link	Future EU medical device nomenclature - Description of requirements	March 2018