MD Law.eu

Information Platform on EU Medical Devices Regulation

MDR/IVDR
IMPLEMENTATION TOOLS

MARCH 2020

Unique Device Identifier (UDI) under MDR/IVDR

POWERED BY OBELIS GROUP

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Agenda

- Background
- UDI: What is it?
- Objectives of the UDI
- MDR and IVDR Regulation – Main Articles and Annex concerned
- When do I need a UDI?
- Where to get a UDI for my device?
- UDI and UDI-DI
- UDI Elements: Unique device identifier
- UDI Elements: UDI carrier
- UDI Elements: UDI database (UDI-DI)
- Basic set of data to be registered in UDI database for medical devices
- Basic set of data to be registered in UDI database for in vitro diagnostic medical devices
- Relation between International medical device nomenclature and UDI
- Implementation timeframe
- Preparation for UDI

AUTHOR: ROLAND GERARD - OBELIS s.a.

Some Definitions

- **Automatic Identification and Data Capture (AIDC)** = […]
- **Human Readable Interpretation (HRI)** = […]

Background

The Global Harmonization Task Force (GHTF) adopted a guidance that was last released in 2013 by the International Medical Device Regulators Forum (IMDRF), an international cooperation of regulators made up of industry stakeholders and GHTF successors.

[...]

Unique Device Identifier (UDI)

[...]

AUTHOR: ROLAND GERARD - OBELIS s.a.