Global UDI – Key to Patient Safety

MS LENA CORDIE

QUALITAS PROFESSIONAL SERVICES

Learning Objectives

- **Explain** Unique Device Identification (UDI) Basics
- **Review** of UDI Requirements in the EU
- **Update** on Labeling & Symbols Standards to Support MDR/IVDR
- **Overview** of Global UDI Initiatives

UDI Basics

What is Unique Device Identification?

Method of clearly, distinctly and unambiguously identifying medical devices, components, sets, kits and systems within the healthcare supply & use chains

General term for a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard

What does UDI do?

Provides a **mechanism** for:

- Standard and clear way to document device use
- More accurate reporting, reviewing, and analyzing of adverse event reports
- Reducing medical errors
- Preventing confusion between similar devices
- Effective management of device recalls

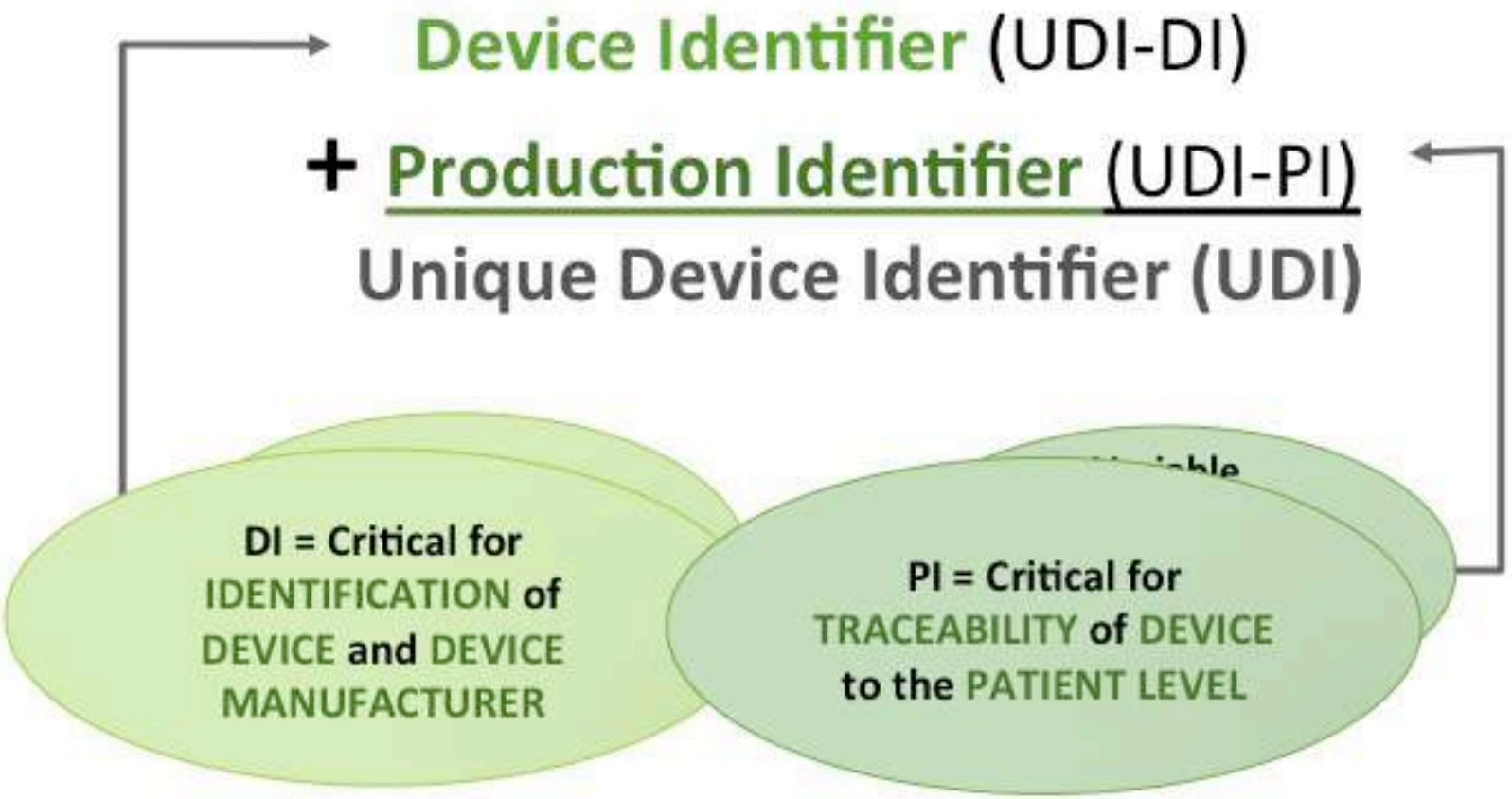
What is a Unique Device Identifier?

AIDC = Automatic Identification & Data Capture

UDI CARRIER

HRI = Human Readable Information

What is in a UDI?



Labeling & Symbols Standards

Are there Barcode Standards?

ISO 15394:2017

- Packaging -- Bar code and two-dimensional symbols for shipping, transport and receiving labels

ISO/IEC 15416 (linear) & **ISO/IEC 15415 (2D)**

- define the quality requirements for linear barcodes and 2D matrix barcodes

ISO/IEC 15426-1 (linear) & **ISO/IEC 15426-2 (2D)**

- define the measuring accuracy of a barcode verifier

ISO/IEC TR 29158:2011

- Direct Parts Marking guideline
- Being replaced by ISO/IEC CD 29158

Are there Barcode Standards for Healthcare?

Accredited Issuing Agencies

Global Standards 1 **(GS1)**

Health Industry Business Communications Council **(HIBCC)**

International Council for Commonality in Blood Banking Automation **(ICCBBA)**

Informationsstelle für Arzneispezialitäten **(IFA GmbH)***

Are there UDI Standards?

International Medical Device Regulators Forum

medical device regulators from around the world working to accelerate international medical device regulatory harmonization and convergence

- Principles of Labelling for Medical Devices and IVD Medical Devices
- Unique Device Identification system (UDI system) Application Guide
- Common Data Elements for Medical Device Identification

http://www.imdrf.org/documents/documents.asp

Are there Labelling Standards?

ISO/DIS 20417

- Medical devices -- information to be supplied by the manufacturer
- Expected to be published in 2020
- Contains requirements for what information is provided by medical device manufacturers:

  Instructions for Use

  Labels

  Marking

  User Manuals

Are there Symbols Standards?

ISO 15223-1:2016

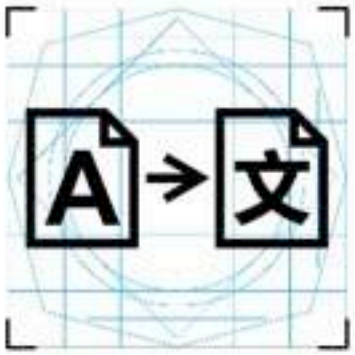
- Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- Revised version expected to be published in 2020
- Contains symbols that convey information on the safe and effective use of medical devices that may be used on the medical device itself, on its packaging or in the associated documentation
- Contains 20 new symbols to support EU MDR/IVDR requirements, including Patient Implant Card

MedTech Europe: Use of Symbols to Indicate Compliance with the MDR (May 2019)

https://www.medtecheurope.org/resource-library/use-of-symbols-to-indicate-compliance-with-the-mdr/

What are the new symbols?

Single patient – multiple use
GRRP WG (PD1)/N52: July 2018), Art. 5.2.17:



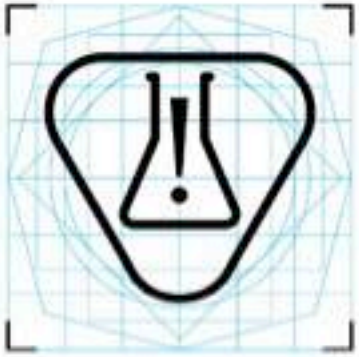
Translation by entity other than manufacturer
MDR Art. 16, point 3 a

Medical device
MDR, Annex 1, 23.2, q.

What are the new symbols?

Contains biological material of animal origin
MDR, Annex 1, 23.2, e.

Contains biological material of human origin
MDR, Annex 1, 23.2, e.

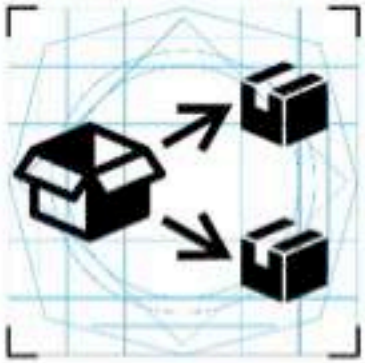


Contains hazardous substances
MDR Annex 1, 23.2.(f)

What are the new symbols?

Sterilized using vaporized hydrogen peroxide
MDR, Annex I, 23.2, l.

Patient name
Annex 2, implant card



Repackaging by entity other than manufacturer
MDR Art. 16, point 3 b

What are the new symbols?

Unique device identifier

Patient information website
Annex 2, implant card

Contains human blood products or plasma derivatives
MDR, Annex 1, 23.2, e.

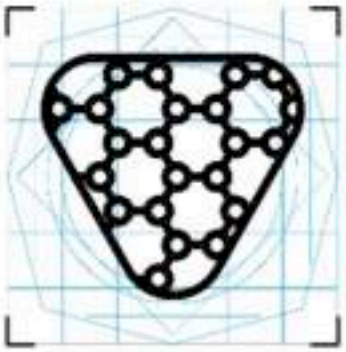
What are the new symbols?

Distributor

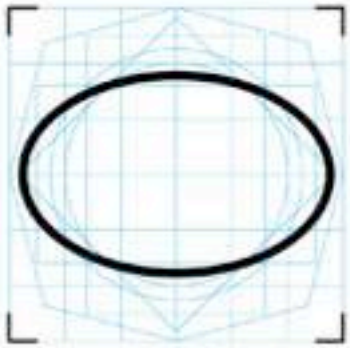
Importer

Contains a medicinal substance
MDR, Annex 1, 23.2, e

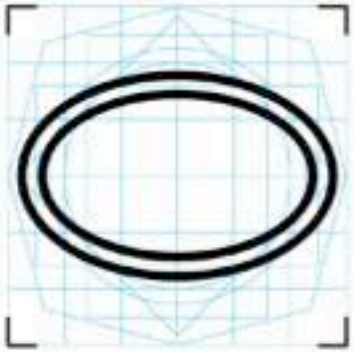
What are the new symbols?



Contains nano materials

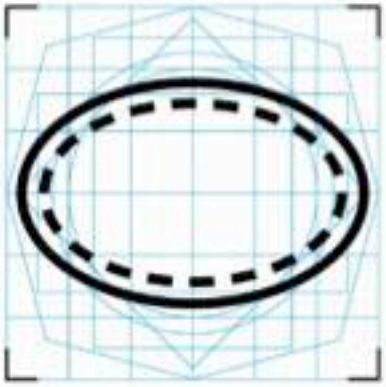


Single sterile barrier system

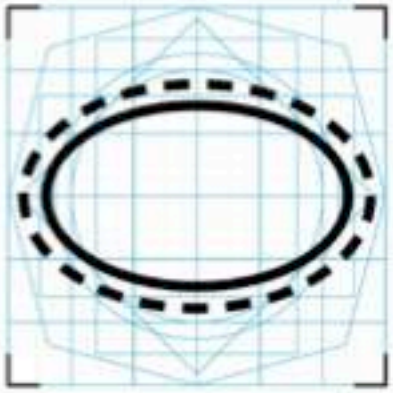


Double sterile barrier system

What are the new symbols?

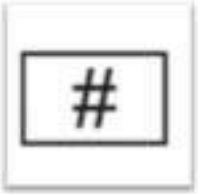


Single sterile barrier with protective packaging inside



Single sterile barrier with protective packaging outside

What are the additional symbols for the Patient Implant Cards?



Model Number:
ISO 7000-6050

identify the model number or type number of a product

Country of manufacture:
ISO 7000-6049

CC is replaced by the two or three letter code defined in ISO 3166-1

Date:
IEC 60417-5662

identify the date that information was entered, or a medical procedure took place

Health care centre or doctor:
ISO 7001-Pi PF 044

identify the date that information was entered, or a medical procedure took place

Patient identification:
IEC 60417-5664

indicate the address of the health care centre or doctor where medical information about the patient may be found

UDI Requirements in the EU

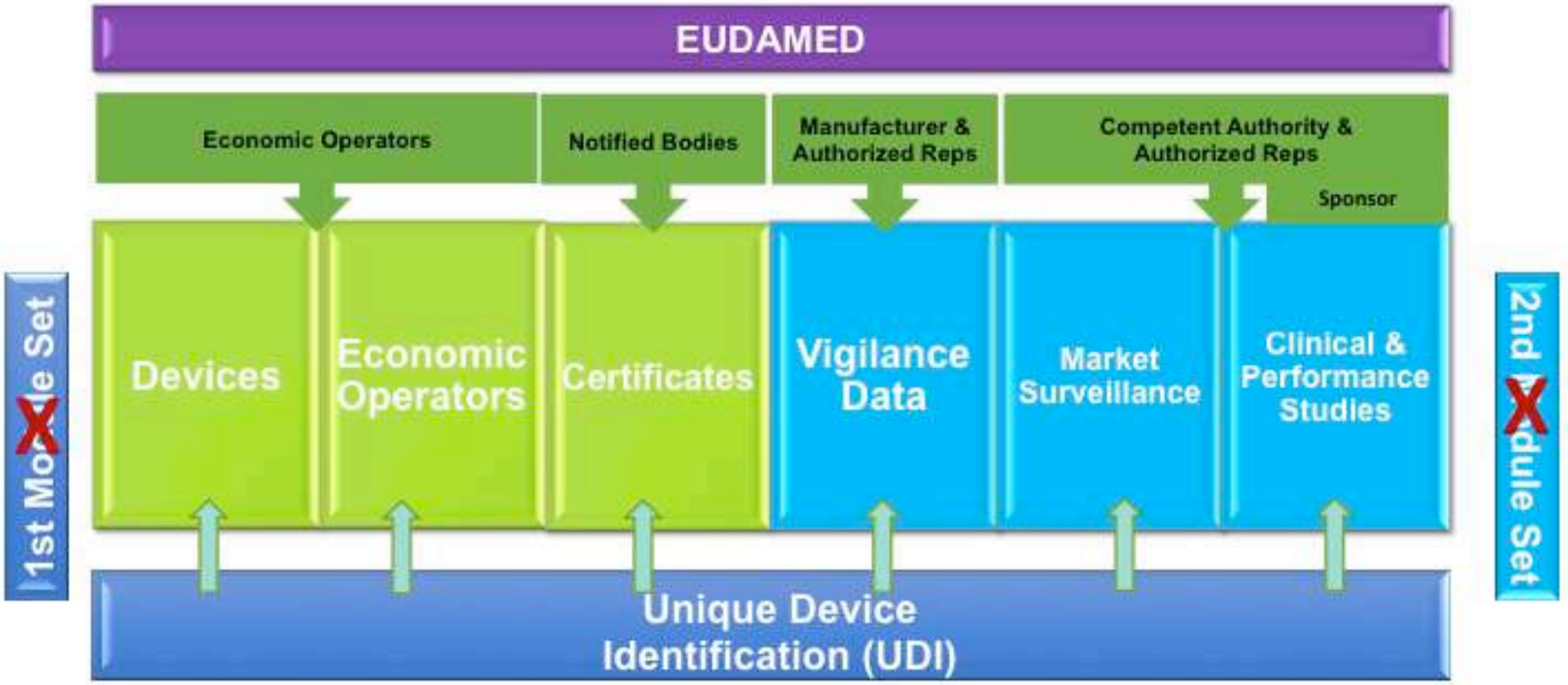
EU UDI Implementation Timelines

Device Class	Labels & Packaging	Direct Marking (reusable devices)	Assigning Basic UDI & UDI-DI
Implantable & Class III	26 May 2021	26 May 2023	26 May 2020
Class IIa and Class IIb	26 May 2023	26 May 2025	26 May 2020
Class I	26 May 2025	26 May 2027	26 May 2020

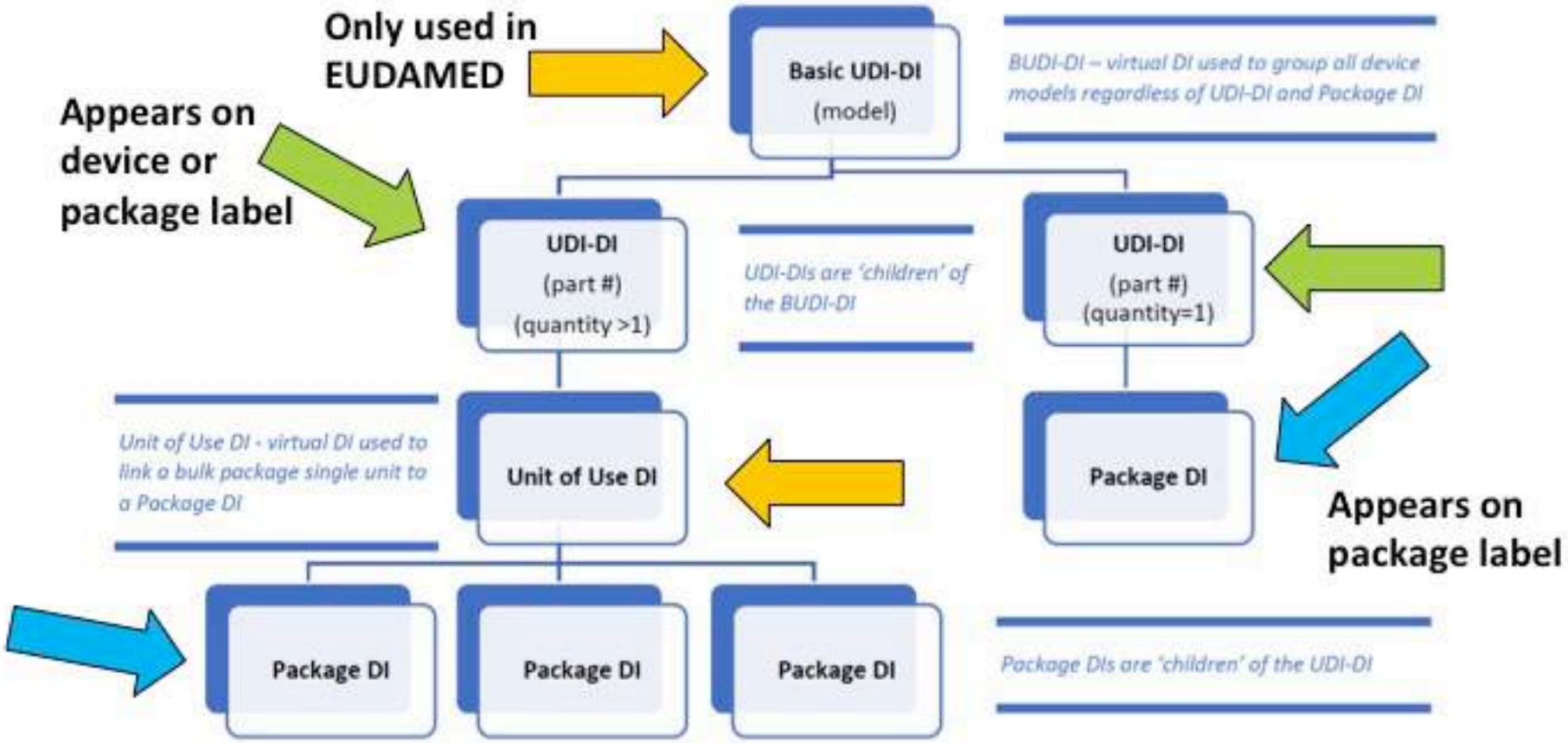
- Legacy devices are not subject to UDI obligations, other than registration in EUDAMED

EUDAMED Database: ~~26 November 2021~~ 26 May 2022

What is EUDAMED?



How does UDI work in EU?



Global UDI Initiatives

AUSTRALIA

Draft proposal published 7 January 2019

Intended to be based on IMDRF UDI Guidance

Apply to all devices placed on the market except:

- custom-made devices
- devices not regulated as medical devices in other jurisdictions
- *possibly* Class I medical devices

Staged implementation

Provide public access to core data elements in AusUDID, excluding UDI-PI and commercial information

BRAZIL

Resolution RDC 232/2018 - expected to go into force in 2020

Applies to for high-risk devices including stents and implants

Harmonized with IMDRF UDI guidance

RNI System = UDI database

Barcode to include device identifier, expiration date and lot or serial number

- No other barcode can appear on the tracking label

Provide three copies of tracking label

- medical records
- patient documents
- legal/ financial documents

CANADA

UDI is still not required for devices marketed in Canada

Will rely on IMDRF principles – no Canadian-specific requirements

December 2019 - accessible database that contains medical device incident reports in a user-friendly, searchable, online format

Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices – Section 21(1)(c):

- mentions 'identifier' as unique number assigned to the device … will permit a device to be distinguished from all other devices.

CHINA

UDI Pilot Program in process

July 2019 - UDI pilot begins

August to November 2019 - organize and verify the creation and assignment of UDI

December 2019 to February 2020 - organize and verify uploading, downloading and interface standards of UDI database

March to June 2020 - organize and verify interdepartmental linkage and expansion application of UDI data

July 2020 - hold the pilot summing-up meeting to form pilot reports and to improve the implementation scheme of the first batch of products with UDI

1 August 2020 – UDI for high risk devices

INDIA

Medical Device Rules 2017

Effective 1 January 2018

CHAPTER VI LABELLING OF MEDICAL DEVICES

46. Unique device identification of the medical device

Explanation.— For the purposes of this rule:

(i) "device identifier" means a global trade item number;

(ii) (ii) "production identifier" means a serial number, lot or batch number, software as a medical device version, manufacturing and/or expiration date.

UDI on all licensed devices by January 1, 2022

JAPAN

March 1999 – began using EAN-128 barcodes

- GTINs used on all reimbursable products

December 2000 – MEDIS-DC (available to public)

March 2008 = MHLW notification "*Barcode marking and database registration*"

December 2013 - *Technical Guideline on Direct Marking for Two-Dimensional Symbol on Steel Instruments* (Ver.1.1)

March 2016 – UDI operation manual issued

- Based on IMDRF UDI Guidance in preparation for international harmonization

Requires use of GS1 standards only for medical devices

SAUDI ARABIA

Application date of UDI Requirements: to be announced

Supports and promotes the IMDRF UDI initiatives

Applies to medical devices, IVDs, kits, configurable devices, and accessories placed onto the market or put into service in the KSA

SAUDI-D = Saudi Arabia UDI Database

UDI-PI may also contain quantity or internal reference number

UDI linear barcodes must be concatenated into a single barcode

Barcodes shall be verified according to the appropriate ISO/IEC standard and meet the issuing agency's grading standards

SOUTH KOREA

National Institute of Medical Device Safety Information (NIDS) – established in 2017 under South Korean Medical Devices Act

UDI requirements will come into force on a rolling basis:

- 2019 for Class IV and high-risk devices
- 2020 for Class III devices
- 2021 for Class II devices
- 2022 for low-risk Class I devices.

Need to report on the number of manufacturer's products provided to medical facilities, distributors and lenders are to be

Medical Device Information System (also known as the Medical Device Information & Technology Assistance Center or MDITAC) – UDI database

TURKEY

2017 – UTS Product Track & Trace System

Remaining transition dates:

- Class IIa – 1 June 2019
- Class I – 1 January 2022

Mobile application – allows public to look-up sold or used medical device specified information

Intent and purpose of harmonizing and aligning the Turkish regulatory framework for medical devices with the new EU regulations

Almost identical to the EU Regulation, while also addressing local issues and principles that are specific to Turkey

Introduces international registry systems, such as the Unique Device Identification (UDI) and EUDAMED schemes, on top of the local registration requirement

UNITED STATES

Compliance Year	Labels/Packages Must Have a UDI	Date Formatting (YYYY-MM-DD)	Data Submitted to the GUDID	Direct Parts Marking (DPM)
2014 ✓	Class III	Class III	Class III	
2015 ✓	Implantable, life-supporting & life-sustaining devices	Implantable, life-supporting, life-sustaining devices	Implantable, life-supporting, life-sustaining devices	Life-supporting, life-sustaining devices
2016 ✓	Class II	Class II	Class II	Class III
2018 ✓	Class I & Non-Classified	Class I & Non-Classified	Class I & Non-Classified	Class II
2020	**Class I & Non-Classified**	**Class I & Non-Classified**	**Class I & Non-Classified**	Class I
2022				**Class I**

Grazie!