Coding requirements and deadlines at a glance

The European Medical Device Regulation (MDR)

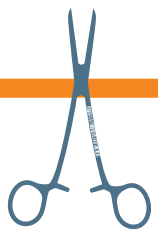
The impending deadlines of the Medical Devices Regulation (EU) 2017/745 will require manufacturers to apply specific codes called unique device identifiers (UDIs) to medical devices that are distributed in the EU.

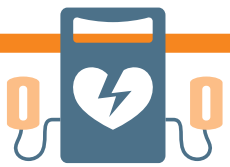
This summary is for informational purposes only and is not intended as legal advice. For a complete description of the Medical Device Regulation (EU) 2017/745, go to: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

In which risk classes are medical devices classified?

Some examples include:

Class I (low risk)	Class IIa (moderate risk)	Class IIb (moderate risk)	Class III (high risk)
Reusable Surgical Instruments	Dental Materials	Pacemakers	Heart Catheters
Elastic Bandages	Hearing Aids	Automated External Defibrillators	Artificial Joints
Disposable Gloves	Contact Lenses		Coronary Stents
	Diagnostic Ultrasonic Devices		Absorbable Implantable Surgical Suture Material
			Heart Valves
			Breast Implants



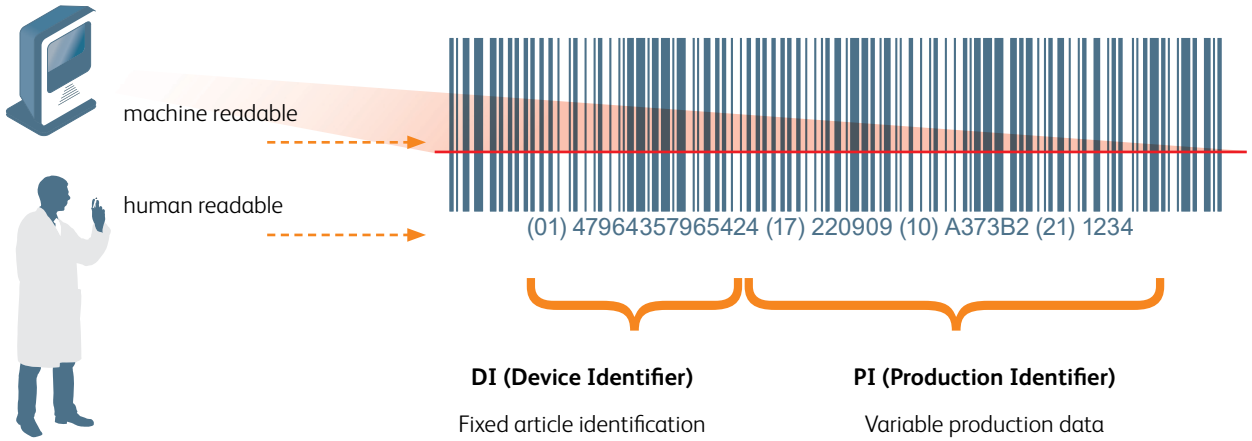


What is a UDI code?

A UDI (Unique Device Identifier) consists of a fixed Device Identifier (DI) and a variable Production Identifier (PI).

This information must be provided in both a human-readable (plain-text) form and a machine-readable form that uses automatic identification and data capture (AIDC) technology.

Example of the GS1-128 linear bar code commonly used to capture UDI code.



DI (Device Identifier)

Fixed article identification number unique for each packaging level of a product.

- (01) Global Trade Item Number (GTIN)

PI (Production Identifier)

Variable production data

- (10) Lot or batch number
- (17) expiry date
- (11) date of production
- (21) serial number (mandatory for implants)

Example of the commonly used GS1 DataMatrix code for capturing UDI code

Where should UDI codes be applied?

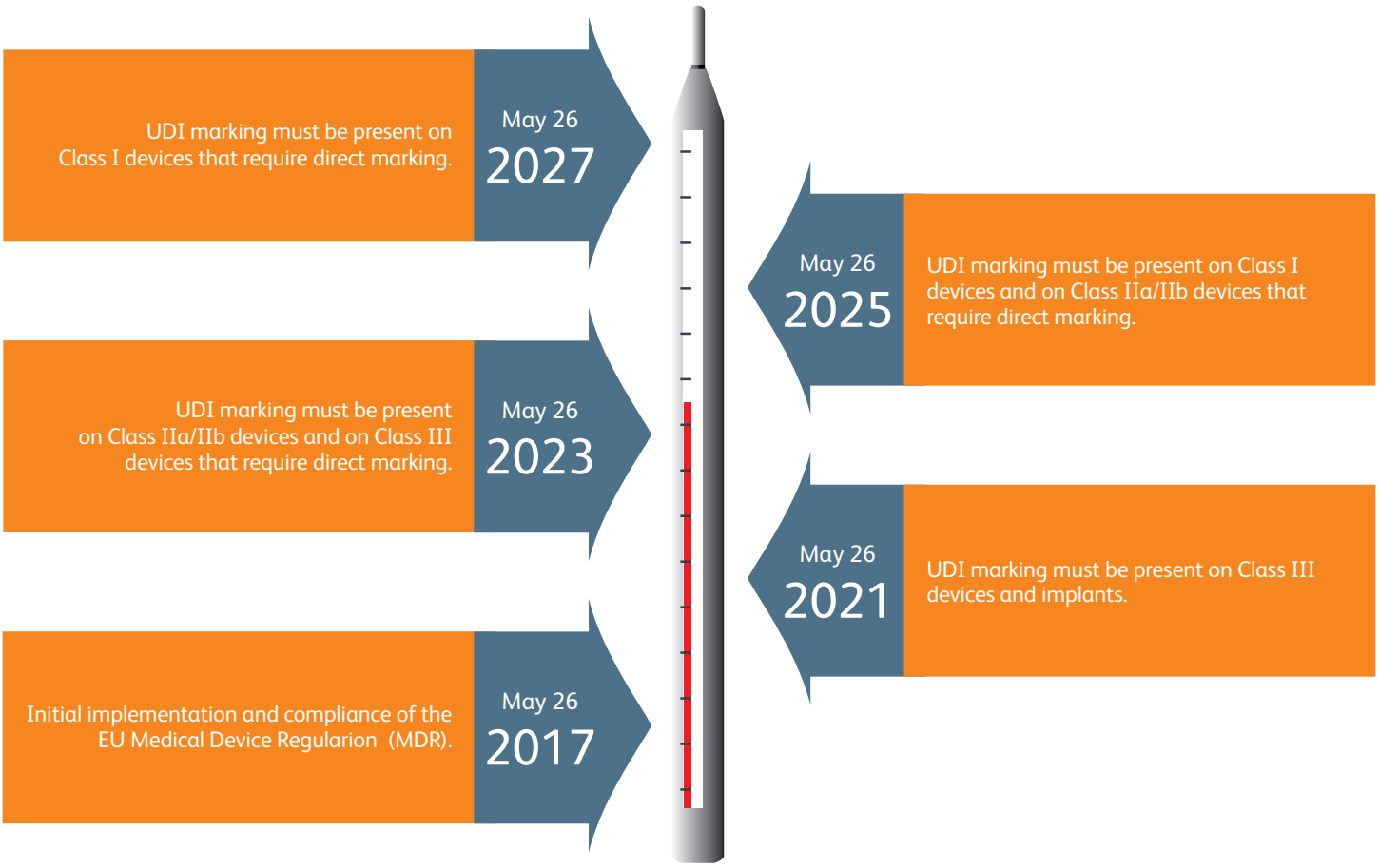
In general, a UDI code must be placed on primay packaging of the device and on all higher levels of device packaging. Shipping containers are not considered to be a higher level of device packaging.

Because the GTIN (Global Trade Item Number, an identification number issued by GS1) is unique for each level of device packaging, the UDI code is unique for each packaging level as well.

Some exemptions:

- In the event of there being significant space constraints on the primary packaging, the UDI code may be placed on the next higher packaging level.
- For single-use disposable Class I and IIa devices that are packaged individually, such as latex gloves, the UDI code can be placed on the next higher packaging level.
- In the case of reusable medical devices, such as surgical instrument, the UDI code must be place directly on the device itself, unless any type of direct marking would interfere with the safety or performance of the device, or the device cannot be directly marked on because it is not technologically feasible.

Keep an eye on the MDR timeline for coding requirements



Select the appropiate printing and marking equipment for applying the right codes

High-qualtiy codes on paperboard, plastic, labels and specialty medical packaging materials

Laser
A beam of infrared light creates marks where the beam interacts with product and packaging surfaces. Features high mark quality, permanence and few consumables.

Thermal Inkjet (TIJ)
High-resolution, ink-based, non-contact printing for coding on flat substrates like Tyvek® and porous/non-porous cartons. Prints traceability information including 2D DataMatrix codes.

Continuous Inkjet (CIJ) and Traversing CIJ
A versatile coding solution, CIJ employs fluids for non-contact printing of up to five lines of text, as well as linear and 2D bar codes. Can print on stationary packaging via traversing systems

Thermo Transfer Overprinter (TTO)
A digitally controlled printhead precisely melts ink from a ribbon directly onto flexible films to provide high-resolution, real time prints.

Label Printer Applicator (LPA)
Prints and places labels on cases of various sizes for traceability throughout the supply chain.

Large Character Marking (LCM)
Ink-based, non-contact printing of alphanumeric codes, logos and bar codes on cases.

Coding technologies for your packaging type:

Printing application	Laser	TIJ	CIJ	TTO	LPA	LCM
Folding carton	✓	✓				
Foils		✓	✓	✓		
Tyvek®		✓		✓		
Labels	✓	✓	✓	✓		
HDPE and LDPE	✓		✓			
Stainless steel	✓					
Shipping cartons	✓				✓	✓

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