

Unique Device Identification: Get to know UDI



UDI is a unique device identification system created and regulated by the U.S. Food and Drug Administration (FDA). It is designed to adequately identify medical devices through their distribution and use. When fully implemented, most medical devices will include a unique device identifier in human and machine-readable forms. When required, these identifiers must not only appear on labels and packaging, but on the devices themselves.

This summary is for informational purposes only and is not intended as legal advice. For a complete description of the Unique Device Identification system, go to: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>

What is a medical device?

Examples include:

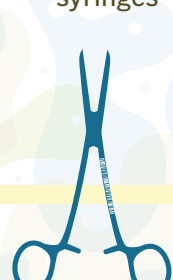
Class I (low-risk)

elastic bandages
examination gloves
dental floss



Class II (moderate risk)

infusion pumps
surgical sutures
syringes



Implantable life-supporting and life-sustaining devices

pacemakers
automated external defibrillators



Class III (high risk)

replacement heart valves
knee prostheses
pacemaker batteries
cochlear implants



What is a UDI code?

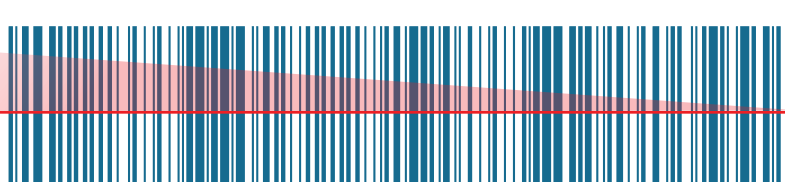
On each medical device, label and package subject to the regulation, a UDI code must be provided in a **human-readable (plain-text) form**. It also must appear in a **machine-readable form** that uses automatic identification and data capture (AIDC) technology.

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



machine readable

human readable



DI (Device Identifier)

Mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.

PI (Production Identifier)

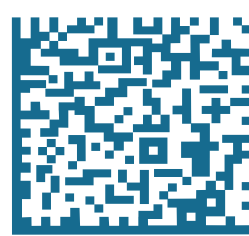
A conditional, variable portion of a UDI that may include one or more of the following:

- lot or batch number (10)
- serial number (21)
- expiration date (17)
- date of manufacture (11)
- distinct identification code for a human cell, tissue, or cellular and tissue-based product

Example of the commonly used GS1 DataMatrix code for capturing UDI



machine readable

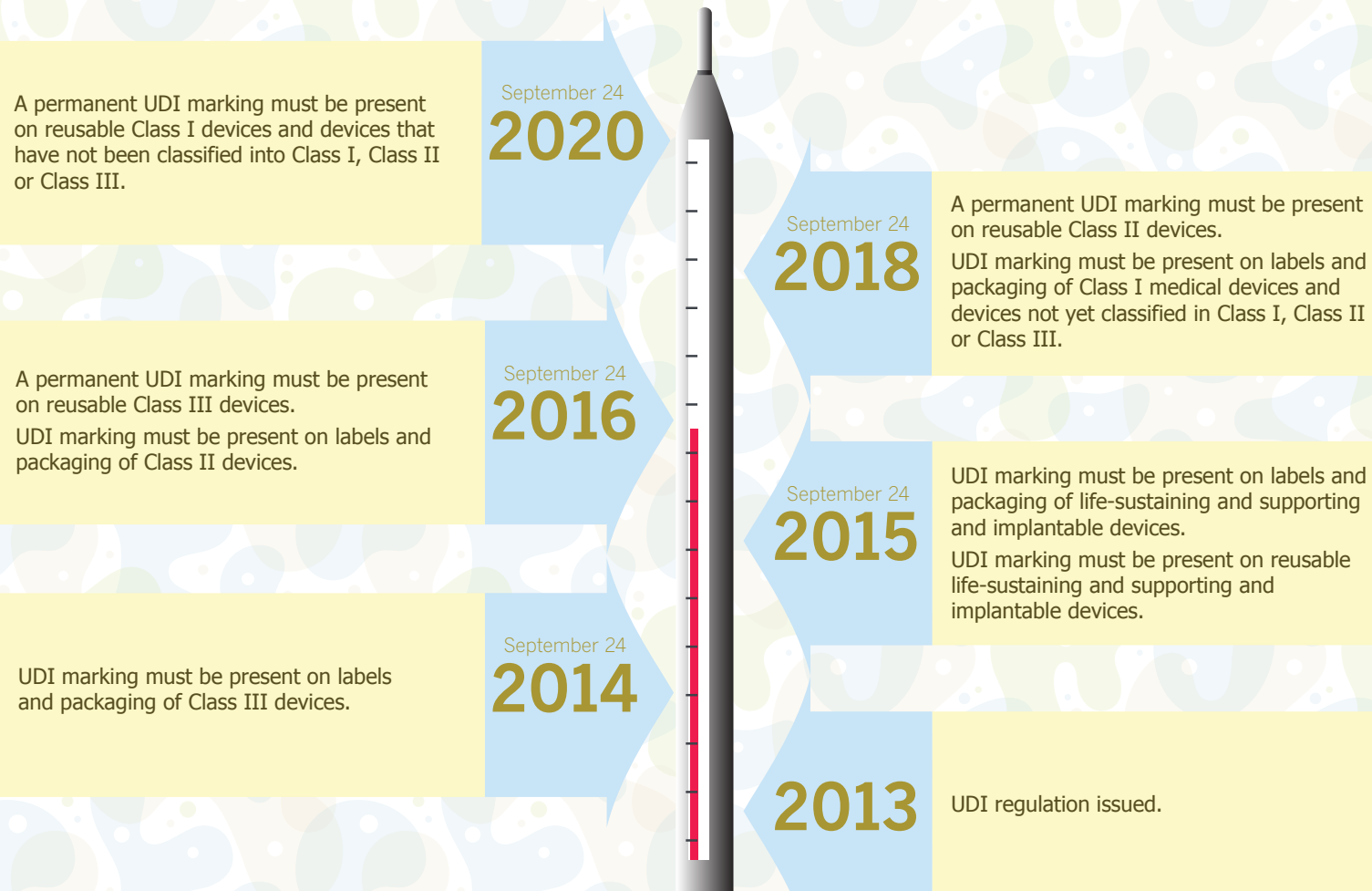


(01)47964357965424
(17)220909
(10)A373B2(21)1234

human readable



Keep an eye on the UDI timeline for coding requirements



Check the FDA's website for updates to the timeline

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ComplianceDatesforUDIRequirements/default.htm>

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



Meet the demand for accurate codes on paperboard, plastic, glass, labels and specialty medical packaging materials



Laser

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



Thermal Ink Jet (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 Ink Jet (CIJ) and Traversing CIJ

A versatile coding solution, CIJ employs CIJ 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.



Thermal 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
Cartons	✓	✓	✓			
Labels	✓	✓	✓	✓		
Tubes	✓		✓			
Pouches & Barrier Materials		✓	✓	✓		
Cases					✓	✓

Learn more about coding on medical devices

Visit www.videojet.com/medical-devices

+971 50 199 6914

MEA.Sales@videojet.com



© 2017 Videojet Technologies Inc. All rights reserved.

Tyvek® is a registered trademark of E.I. du Pont de Nemours and Company