# 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)

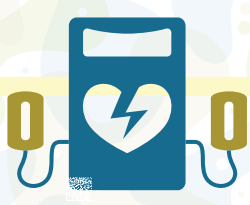
elastic bandages
examination gloves
dental floss

### Class II (moderate risk)

infusion pumps
surgical sutures
syringes

### Implantable life-supporting and life-sustaining devices

pacemakers
automated external defibrillators



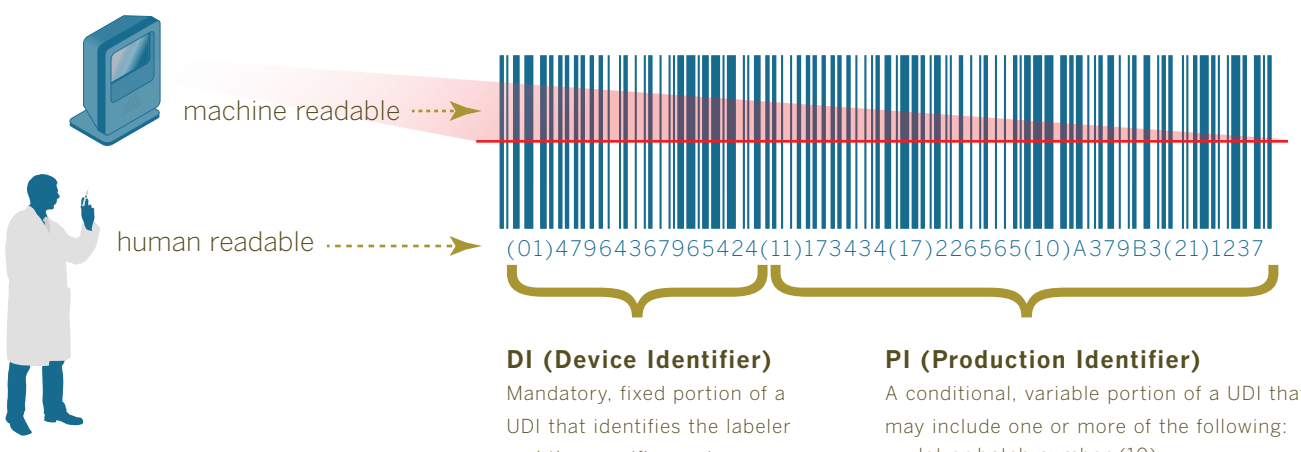
### Class III (high risk)

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




**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


## Keep an eye on the UDI timeline for coding requirements

**September 24, 2020**
A permanent UDI marking must be present on reusable Class I devices and devices that have not been classified into Class I, Class II or Class III.

**September 24, 2018**
A permanent UDI marking must be present on reusable Class II devices.
UDI marking must be present on labels and packaging of Class I medical devices and devices not yet classified in Class I, Class II or Class III.

**September 24, 2016**
A permanent UDI marking must be present on reusable Class III devices.
UDI marking must be present on labels and packaging of Class II devices.

**September 24, 2015**
UDI marking must be present on labels and packaging of life-sustaining and supporting and implantable devices.
UDI marking must be present on reusable life-sustaining and supporting and implantable devices.

**September 24, 2014**
UDI marking must be present on labels and packaging of Class III devices.

**2013**
UDI regulation issued.

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 product and 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 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.

**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

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