Laser Marking +
Engraving Solutions

FOBA®
Laser at your service

Unique Device Identification – UDI
Clear Identification of Medical Devices

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 form. When required, these identifiers must not only appear on labels and packaging, but on the devices themselves as in the case of repeatedly used equipment (i.e. surgical tools, instruments) which has to be marked directly.

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?*

Class I	Class II	Class III
low risk devices, general controls	moderate risk devices with general controls and special controls	high risk, general controls and premarket approval, life-supporting, life-sustaining
→ elastic bandages → examination gloves → dental floss → stethoscope	→ infusion pumps → hearing aids → surgical sutures → syringes	→ heart valves → knee prostheses → implantable pacemakers → automated external defibrillators

* The classification system of medical devices differs slightly in the US and in the EU. The EU lists 4 Classes (Class I, IIa and IIb and III) ranging from low risk to high risk. For the US the FDA defined three risk classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device.

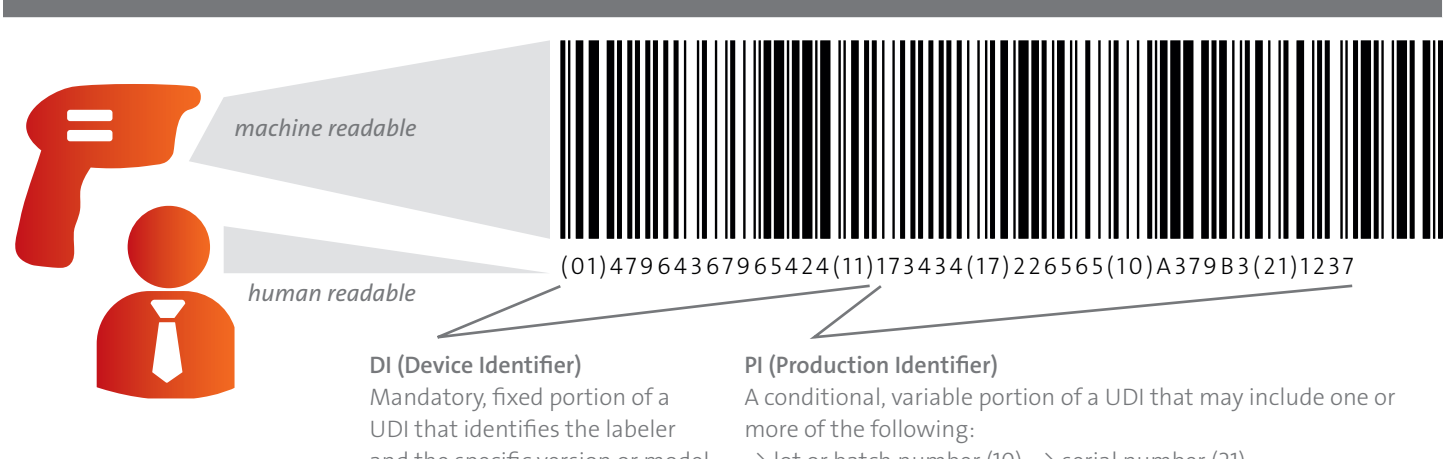
What is a UDI code?

The FDA's final UDI rule „requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement." The label and device package of each medical device have to include a UDI code which must be provided in a human-readable (plain-text) form and in a machine-readable form that uses automatic identification and data capture (AIDC) technology. The UDI code will also be required to be directly marked on a device that is intended for more than one use, and intended to be reprocessed before each use.

Source → https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system

UDI code examples

GS1-128 LINEAR BAR CODE (commonly used to capture UDI)

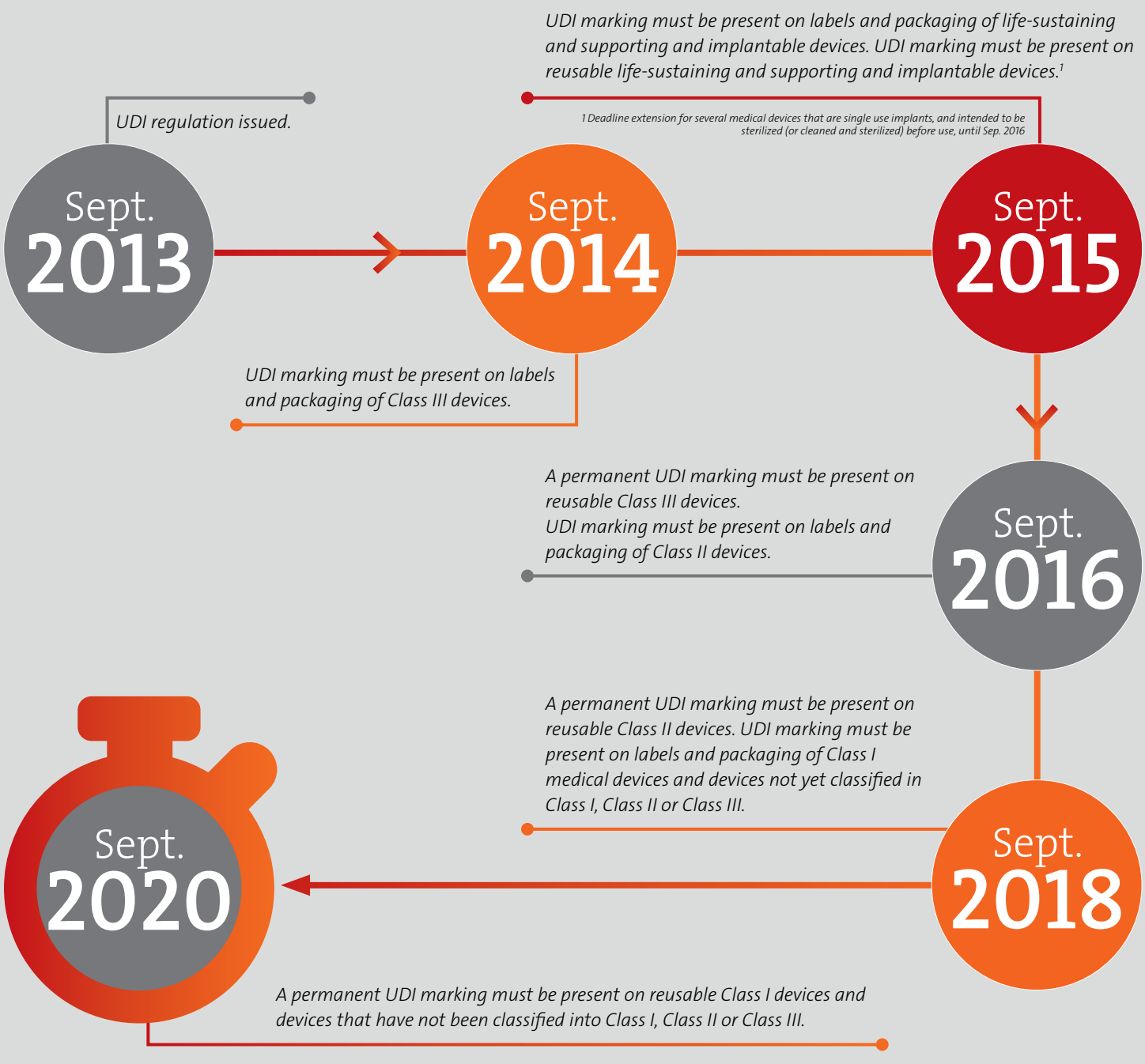


DI (Device Identifier)
Mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.

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

GS1 DATAMATRIX CODE (commonly used to capture UDI)

UDI implementation timeline*
High risk devices first!



→ Check www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm for updates to the timeline

* UDI timeline for medical devices and products manufactured in and imported to the United States. For the EU, a corresponding UDI identification rule is in preparation. The European Commission has already layed the foundations for an upcoming directive after which's adoption manufacturers will probably have 5 years for registration and implementation.

The ideal equipment for applying UDI codes:
A marking laser

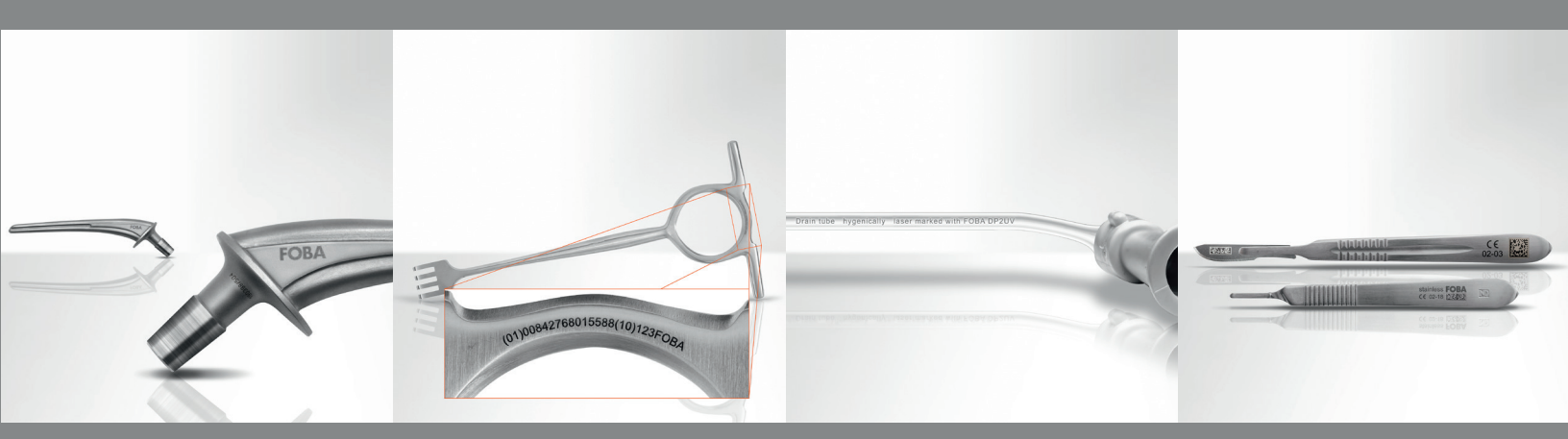
Meet the demand for accurate codes on almost any medical packaging and medical device materials:

→ Laser marking is ideal for direct part-marking in order to comply with UDI. It is fast and economic, allows variable data printing for serialization, and is well suited for volume production.

A beam of laser light creates marks where the beam interacts with product and packaging surfaces. Laser marking features high mark quality, permanence, highest accuracy and process stability when combined with vision, and few consumables.

Umbilical cord scissor with annealed UDI code

Learn more about laser marking medical devices:
Visit → www.fobalaser.com/industry-solutions/medical-technology/



ALLTEC GmbH | FOBA Laser Marking + Engraving
An der Trave 27-31 | 23923 Selmsdorf | Germany
T +49 38823 55-556 | F +49 38823 55-222
info@fobalaser.com
www.foba.de | www.fobalaser.com | www.foba.it

HIBC APPROVED SOLUTION PROVIDER
GS1 Germany SOLUTION PROVIDER FOBA Laser Marking + Engraving Alltec GmbH
TÜVRheinland ZERTIFIZIERT Management System ISO 9001:2008 www.tuv.com ID 9105014806