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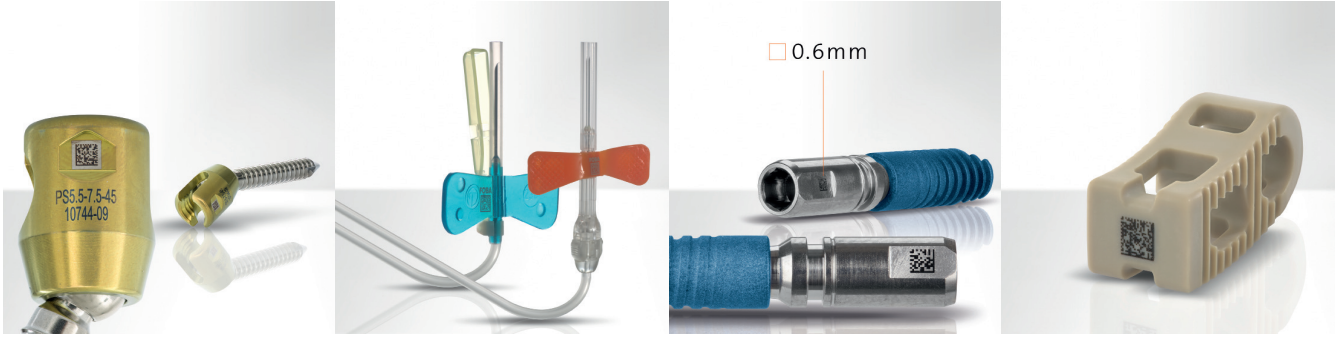
Medical Industry White Paper

Unique Device Identification (UDI)
Requirements, deadlines, secure labeling according to FDA and MDR

The implementation of the UDI Directive is mandated for medical device manufacturers. This has been in effect since 2014 for companies selling their products on the American market, and, as of 2020, also in the EU and other countries. Medical products must be clearly identified to ensure reliable traceability and patient safety. In addition to the marking of packaging and labels, this also applies to the direct marking of high risk devices such as implants and instruments. Manufacturers must maintain deadlines and need to implement marking systems that are able to mark in accordance with UDI requirements and medical standards. In order to fulfill the demanding labeling, serialization and marking requirements, appropriate technologies must allow for the application of high resolution codes with long-term durability, even in the smallest of spaces, while additionally providing a verification process to read back code contents and quality.

Laser marked UDI codes



The UDI program: effective since 2014 in the USA

Consistent labeling of medical devices for an increase in patient safety and transparency in the supply chain

In 2013, the FDA (Food and Drug Administration) released the UDI Directive for the uniform labeling of medical devices with the marking specification in its "final rule". Standardized labeling is meant to enable the complete identification and tracking of medical devices throughout the entire product life cycle. In 2017, the European Union and other countries closed the gap and implemented an equivalent, the Medical Device Regulation (MDR).

The **UDI system came into effect in stages**, over a period of seven years, **based on product risk level**, starting with the products of the highest risk class. The directive applied initially to the American market – that is to say for medical products and devices that are produced or imported and distributed in the USA.
Labeling requirements are also being introduced by means of the new European Medical Device Regulation to anchor UDI standards internationally. During a transition period from 2017 to 2020, old and new regulations applied simultaneously.

The declared goal of the UDI system is to increase patient safety and optimize patient care.
The UDI system addresses all of the following aspects:

- More efficient product recalls
- Improved counterfeiting protection
- Simplification of data entry and accessibility with different systems
- Security throughout the entire supply chain
- Field Safety Corrective Actions – FSCA
- Better identification, documentation and prevention of incidents
- Reducing the chances of medical errors occurring (by quick and concise product identification, and the ability to easily obtain important product information > Reducing number of misapplications)

Additionally, the labeling system allows for the simplification of logistics, ordering and delivery processes.

FDA

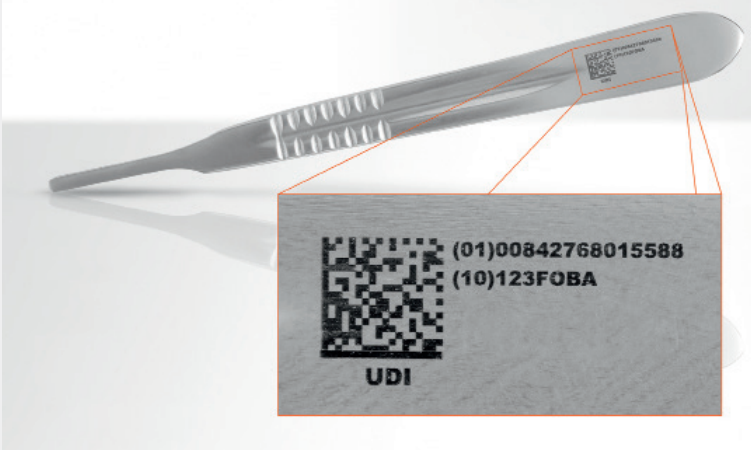
IMDRF International Medical Device Regulators Forum

Background

The UDI system has emerged from an initiative set by the legislators of the countries that form the IMDRF (International Medical Device Regulatory Forum). As the first membership country in the IMDRF to do so, the US implemented the UDI system, with the start date of 24 September 2014, into law.

The implementation is the responsibility of the FDA (Food and Drug Administration) and concerns medical products sold in and imported into the American market.

→ *FDA informationen under: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/*



UDI in the European Union – Medical Device Regulation (MDR)
"System of a unique product number" as of 2020

In the EU, the UDI directive has been introduced as a "Unique Device Identification" system within the framework of the new European Medical Device Regulation (Medical Device Regulation - MDR) in 2017. After a transition period of three to five years, the MDR will become effective in stages for all risk classes as of May 26, 2020.**

** Regulation 2017-745 on medical devices of 5 April 2017 (versions in English and other languages) → https://eur-lex.europa.eu/eli/reg/2017/745/oj*

In Europe, the implementation and introduction of a UDI regulation is the responsibility of the European Commission. **For a long time, uniform guidelines for the traceability of medical devices did not exist**; the various member countries developed different regulatory mechanisms, or did not regulate traceability at all. (See Official Journal of the European Union > 2013/172/EU, L 99/17)[1]

In its proposal for a regulation on medical devices[2], the European Commission created Chapter III of the "Identification and Traceability of Products". Article 24 deals with the **"system of the unique product number"**, which is intended to enable the identification of medical products and facilitate their traceability. This is not intended to regulate all aspects of the UDI system, but concerns itself more with the compatibility of the traceability mechanisms at the national and/or regional level and the introduction of an obligatory, internationally compatible UDI system (see Official Journal of the EU > 2013/172/EU, L 99/18)[1].

[1] *Official Journal of the EU (2013/172/EU):*
→ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:DE:PDF

The **UDI** regulation will be introduced with the new European Medical Devices Regulation, **will apply to all medical products and require the re-certification of products (MDR certificate).** For manufacturers this means (among other things):

- → technical documentation has to be revised
- → each product must be assigned a unique product identification number ("unique device ID")
- → manufacturers must register themselves and EU-marketed products in the EU database EUDAMED
- → medical products may have to be re-labeled and marked (per the new legislation, after the respective transition period, products will be required to carry a certificate when they are brought to market in the EU)

The new MDR entered into force in March 2017. **Directly marked UDI codes have to be applied between 3 to 7 years after date of MDR implementation – from 2023 to 2027, depending on risk-classes.**

[2] Proposal for a Regulation on medical devices:
→ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_10617_2016_INIT

CE labelling

Currently, medical products – in order to be marketed or put into service on the European market – must bear a CE marking. This can only be applied if a conformity assessment procedure demonstrates that the product complies with the basic safety and performance requirements laid down in the relevant European directives. Requirements include a risk management, a clinical evaluation and a risk-benefit analysis.

The conformity assessment procedure must be carried out in accordance with the risk class of the medical device, with the participation of a privately operating, independent testing and certification body (known entity) which is subject to a state designation and reports to the appropriate authority.

Only for risk class I products can the manufacturer carry out the procedure in direct responsibility and without involving a notified body.

→ ***CE marking and conformity declarations*** *document compliance with essential safety and performance requirements. Manufacturers, whose products are already certified accoding to EN ISO 13485 are well prepared for the certification according to MDR.*

CE

UDI codes on packaging or as direct marking:
Risk classes determine compliance dates

Where and when a UDI code has to be applied to a product depends on its nature (risk class) and intended use. The UDI system differentiates between the marking of the packaging or labels and direct marking on the product.

According to the FDA, the last deadline for the marking of **packaging and labels** had been reached in **September 2018.** UDI **direct part marking** for all risk classes in the USA will be due at latest by **September 2022.**

According to the MDR, direct marking will not be mandatory immediately on the regulation's kick-off on May 26, 2020 but, depending on the risk classes, will be mandatory as of May 2021 until May 2027 the latest. From then on, the entire range of products and packages will have to bear UDI on the product directly and/or on the packages (see schedule, right).

At that point, the packaging and labels of all class I-III products must carry a UDI code in plain text and machine-readable form, using automatic identification and data collection (AIDC) technology.

Direct part marking is required for implants and those medical products intended to be used over an extended period of time (several months or years) and require reprocessing (i. e. sterilization) before each use, as these will necessarily be separated from the original package.

Recertification of risk class Ir:
For the first time in Europe, class Ir surgical instruments (i. e. scissors, scalpels, forceps, drillers etc.) need to be certified if intended for multiple use after reprocessing/cleaning (according to EU-MDR, appendix IX chapter I+III respective appendix XI (A)).

Before introducing MDR, a certification was required only for risk classes III, II a + b as well as Im/Is. Class I products were allowed to be validated by manufacturers themselves.

As of the MDR enforcement date 2020, a recertification is required for placing a product on the market. Certification is being executed by Notified Bodies, e. g. TÜV (Germany) or BSI (UK).

To keep the certification of their entire product portfolio up to date, manufacturers may now be challenged by additional expenses caused by extended marking and documentation requirements. This concerns the company's data management, IT-systems, QM-processing as well as existing distribution, supplier and QS structures.

Acc. to 21 CFR 801.45 (b) → https://www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol8/pdf/CFR-2014-title21-vol8-sec801-45.pdf the directly marked UDI code can be either identical with the one on the packaging, or can be a different one in order to distinguish the packed device from the unpacked product.

MDR: Lack of Notified Bodies for the recertification of Ir products

Manufacturers depend on Notified Bodies when it comes to pass a product through a certification procedure. Notified Bodies are officially recognized private enterprise institutions that are assigned to control and verify manufacturer's compliance in the fields of cleaning, disinfection, sterilization, maintenance and functional testing. According to the MDR, all existing Notified Bodies must run through another recertification by the due date of May 26, 2020. This is estimated to be critical also for the recertification of a significant number of class Ir products.

Many experts asked for a deadline extension of current due dates to prevent the bottelneck. According to the resulting corrigendum dated Nov. 22, 2019, class Ir- products may remain on the market even without recertification until latest May 2024 **if they had been certified according to MDD and not been undergoing changes.**

Link to corrigendum: https://data.consilium.europa.eu/doc/document/ST-13081-2019-INIT/en/pdf

List of Notified Bodies in Europe → https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main

FDA and MDR Risk Categories

low risk, general controls	moderate to higher risk, general and special controls	high risk, general controls and premarket approval, life-saving and life-sustaining

→ FDA

Class I	Class II	Class III
→ bandages → stethoscopes → surgical scissors → dental floss → mechanical wheelchairs	→ Infusion pumps → surgical sutures → bone screws → syringes → condoms → powered wheelchairs	→ heart valves → knee prosthesis → pacemakers → automated external defibrillators

→ MDR

Class I	Class IIa/Class IIb	Class III
I: → bandages → wheelchairs → walking frames → patient's beds I r: reusable surgical instruments I m: products with measuring function I s: sterile packed medical products	IIa: → cannulas → dental material → contact lenses → scalpels → ultra-sonic diagnostics → hearing aids IIb: → defibrillators → X-ray technology → dental implants → condoms → nails and plates	→ heart valves → heart catheters → pacemakers → coronary stents → joint prosthesis → breast implants

Medical device classification in the USA and the EU. In the US, the FDA has defined three risk classes based on the degree of control needed to guarantee the safety and efficacy of the products.
The EU distinguishes four classes (Class I, IIa and IIb and III) for low to high risk. Furthermore there is a diversification of class I products which are additionally divided into reusable ("I R"), with measuring function ("I m") and sterile packed (!I s").
Each product gets classified individually according to its special application.

Compliance deadlines for UDI-labelling

1) if reused and reprocessed

FDA	09.2014	09.2015	09.2016	09.2018	09.2022
MDR	05.2021	05.2021	05.2023	05.2025	05.2027
Class III	labels, packages		**direct marking[1]**		
Implantable, life-saving, life-sustaining		labels, packages **direct marking[1]**			
FDA: Class II MDR: Class IIa/IIb			labels, packages	**direct marking[1]**	
Class I and non-classified				labels, packages	**direct marking[1]**

No directly marked UDI is required for sterile packaged implants that are unpacked directly at the implant site. A directly marked UDI code is only required if the corresponding products are processed (for example, cleaned, sterilized or passivated) before their use. Instruments that are repeatedly used and reprocessed must – depending on the risk class – carry a permanent UDI code by 2020 (FDA) or 2027 (MDR) at the latest. For the time being, the FDA (USA) has postponed the marking deadline for reusable class I-products from formerly 2020/21 until September 2022. → http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm

FDA and MDR compliance dates:
All deadlines at a glance

The UDI system is phased in stages based on product classification risk level, starting with the products with the highest risk class. Find below the labeling deadlines for products manufactured in or imported into the United States.

Deadline	UDI Labeling obligations apply to ...
September 24, 2014	→ Labels and packages of class III medical devices (acc. to 21 CFR 801.20) → Devices licensed under the Public Health Service Act (PHS Act), i.e. in-vitro diagnostics for donor screenings (21 CFR 801.20) → Class III stand-alone software (21 CFR 801.50(b))
September 24, 2015	→ Labels and packages of implantable, life-supporting, and life-sustaining devices (21 CFR 801.20) → **Life-supporting or life-sustaining devices** that are required to be labeled with a UDI must bear a **UDI as a permanent marking on the device itself** if the device is **intended to be used more than once and intended to be reprocessed before each use** (21 CFR 801.45) → *Compliance date extension for single use implants that are intended to be sterilized or cleaned and sterilized before use) to September 2016*[1] → Life-supporting or life-sustaining stand-alone software (see 21 CFR 801.50(b))
September 24, 2016	→ **Direct/permanent marking** of **class III devices** if the device is **intended to be used more than once and intended to be reprocessed before each use** (i.e. cardiovascular or neurological catheter) → **Direct/permanent marking** of **single use implants that are intended to be sterilized or cleaned and sterilized before use** → *Compliance date extension from 2015 to 2016!* → UDI on labels and packages of class II medical devices (21 CFR 801.20) → UDI on class II stand-alone software (21 CFR 801.50(b))
September 24, 2018	→ **Class II devices** that are required to be labeled with a UDI must bear a **UDI as a permanent marking**, if the devices are intended to be **used more than once and intended to be reprocessed before each use** (21 CFR 801.45) → Labels and packages of class I products and devices that have not been classified into class I, II, or III → Class I stand-alone software (21 CFR 801.50(b))
September 24, 2022	→ **Class I devices**, and devices that have not been classified into class I, II, or III that are required to be labeled with a UDI, must bear **UDI as a permanent marking on the device itself** if the device is intended to be **used more than once and intended to be reprocessed before each use** (21 CFR 801.45).

[1] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIExceptionsAlternativesandTimeExtensions/UCM423853.pdf

Source: Compliance Dates for UDI requirements (FDA)
→ http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm

List of medical devices that FDA classifies as implantable, life-saving, and life-sustaining devices → http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UCM382463.pdf
FDA's product classification database http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm

There is a transition period of up to four years after the European MDR enters into force, i. e. until May 25, 2024 the hitherto MDD (Medical Device Directory) is still valid. Find hereafter the UDI marking compliance dates for products that are manufactured in or exported to the EU (according to art. 123 para. 3 f-h MDR):

Deadline	Compliance Requirements
May 26, **2021:** entry into force of MDR *(postponed from 2020 due to Corona-crisis)*	→ Application for UDI → Compliance of internal quality management and technical documentation with MDR requirements → Designation of a UDI responsible in the companies → More short-dated report requirements in the case of product defects and obligation to report indidents to the EUDAMED → Post-Market Surveillance/Medical Device Vigilance System: Risk control and patient safety must be indicated within three years after the commercial launch of a product → Newly introduced products need MDR-certification → All existing products products need recertification. For class Ir-products there is a deadline extension until 2024 (see below).
May 26, 2021	→ UDI on labels and packages of class III products
May 26, 2022	→ **Implementation of EUDAMED database** and registration of data into the EUDAMED data base
May 26, 2023	→ **Direct part marking** of class III devices, if the device is inteded to be used more than once over a period of time and intended to be reprocessed before each use → UDI on labels and packages of class IIa and IIb products
May 26, 2024	→ Deadline extension: Class Ir products that have already been approved according to MDD and not been modified can remain on the market and do not have to be recertified until 2024.
May 26, 2024	→ End of disposal of products that have already been approved according to MDD
May 26, 2025	→ **Direct part marking** of class II devices, if the device is inteded to be used more than once over a period of time and intended to be reprocessed before each use → UDI on labels and packages of class I products
May 26, 2027	→ **Direct part marking** of class I devices, if the device is inteded to be used more than once over a period of time and intended to be reprocessed before each use
Last updated: April 2020	

See the Official Journal of the European Union online: "REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)" → https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN

Parts of the MDR with special regards to UDI marking

→ *Art. 27: Unique Device Identification system*
→ *Art. 29: Registration of devices*
→ *Art. 123: Entry into force and date of application*

Reliable and unique:
Code format and structure of a UDI code

Clear regulations apply for UDI codes, since only a uniform code format and reliably readable marks and labels ensure reliable traceability.

According to 21 CFR 801.40, medical devices have to carry a **UDI** that is **represented in two forms**:

→ Easily readable **plain-text** (HRI/Human Readable Interpretation), alpha-numeric characters
→ AIDC technology (Automatic Identification and Data Capture), which means a **machine readable code** (bar code/2D code).

In case the **UDI code is applied as a permanent direct mark**, it must be in either or both (1) easily readable plain-text and (2) AIDC form or alternative technology (see 21 CFR 801.45). Even in the smallest areas, the UDI can be marked as a small format Datamatrix code.

UDI code examples

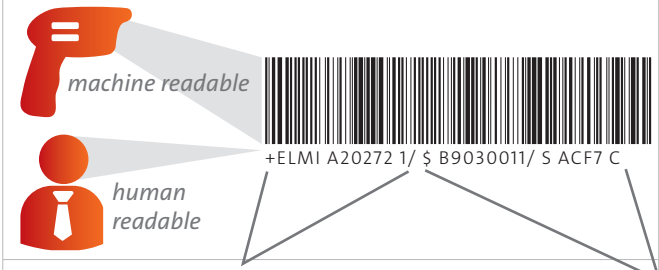
GS1-128 linear bar code

Primary code
DI (Device Identifier)

GS1 DataMatrix code

Secondary code
PI (Production Identifier)

HIBC linear bar code



Primary code
DI (Device Identifier)

HIBC DataMatrix code

Secondary code
PI (Production Identifier)

Code format: UDI = DI + PI

The Unique Device Identifier consists of two parts, the Device Identifier (DI) and the Production Identifier (PI). An exception are Class I medical devices, for which the labeling with the Production Identifier is not required.

The **Device Identifier (DI)** is the mandatory, fixed portion of a UDI that identifies the labeler and the device (specific version or model). The DI contains the following static information:

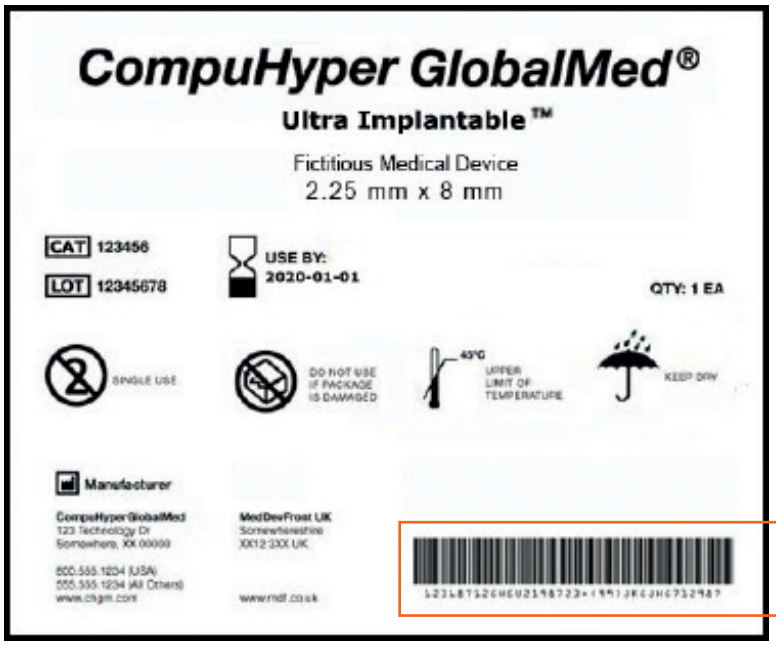
- Identifies the manufacturer/labeler
- Specific version or model of device (also reference code)

This information serves as the key to obtain device information in the UDI database (GUDID). The DI is a globally unique product code which allows for the clear identification of a device.

The **Production Identifier (PI)** is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

- Lot and batch number (GS1 > 10)
- Serial number (GS1 > 21)
- Expiration date (GS1 > 17)
- Date of manufacture (GS1 > 11)
- Unique code for a human cell, tissue, or cellular or tissue-based product

The selection of the related data elements depends on the product (i.e. batch management requirement). The PI data are only deposited in the code, they are not part of the GUDID. The GUDID only tells if they are "existing" or "not existing". The format YYYY-MM-DD applies for all dates in text form (HRI, Human Readable Interpretation), for example, March 2, 2017 must be represented as 2017-03-02 (see 21 CFR 801.18).



→ *More details on the UDI system in Annex VI, Part C of the MDR*

Fictitious example of what a unique device identifier (UDI) would look like on a medical device label.
(Reference: https://www.fda.gov/ucm/groups/fdagov-public/documents/image/ucm368901.jpg)

UDI code/unique device identifier (DI+PI)

Coding system and issuing agency:
International formatting standards for UDI codes

UDI coding for medical products does not implement a new code format, but uses existing standards. Machine readable linear barcodes are in use as well as DataMatrix Codes, both following international standards and enabling product identification throughout the entire product life cycle (see MDR, Art. 27, para. 2).

→ The Unique Device Identifier must conform to international ISO standards (ISO/IEC 15459–2, ISO/IEC 15459–4, ISO/IEC 15459–6) and may only use characters and numbers from the invariant character set of ISO/IEC 646 standard (see 21 CFR 830.20).

A UDI must be issued by a FDA-accredited official institution, by one of the so called "Issuing Agencies".

UDI Issuing Agencies are internationally positioned private enterprise organizations responsible for the assignment of a UDI for every single product. Three of the accredited are:

→ **GS1** (Global Standards One)
→ **HIBCC** (Health Industry Business Communications Council)
→ **ICCBBA** (International Council for Commonality in Blood Banking Automation).

Both, the Health Industry Barcode (HIBC) and the GS1 code are equally suitable for the UDI compliant marking of medical products and devices. With the ISBT 128, the ICCBBA offers a special system for products of human origin (blood, transplants).

UDI: Indispensable in quality management

Internationally applied standards of code formatting make sure that products can be registered on all international marketplaces in a fast, consistent and distinct way. Nationally divergent registration prodedures become thus unnecessary.

Additionally, automated machine-driven data capture can also prevent recording errors.

UDI marking therefore contributes to better efficiency and reliability of all workflows throughout the entire product life cycle. This applies to the fields of production, procurement, delivery, inventory management, customer complaints as well as waste removal. Product traceability is also of increasing significance for hospitals regarding internal logistics and administration.

FOBA is **GS1 Germany Solution Partner** *and* **HIBC Approved Solution Provider**
→ *https://www.fobalaser.com/about-foba/certifications/*

HIBC (Health Industry Barcode) or GS1 for UDI marking on medical products

HIBC *was developed in 1986 especially for the traceability of medical devices within the industry and inside hospitals. Today the HIBC code is also being applied in several other sectors.*

Due to the availability of up to 18 alpha-numeric characters it is possible to display all necessary contents as well as the proper item number.

HIBC is being assigned by HIBCC (Health Industry Business Communications Council) and follows the standards of ANSI (American National Standards Institute) and of CEN (European Committee for Standardization). Several international health organizations belong to the HIBCC network.

GS1 *uses a special and individually allocated GTIN (Global Trade Item Number) of 13 digits for each product and each packaging unit.*

The GS1-System has been in existnce in its current state since 2005 as an issuing agency for product numbers, originally with the purpose of introducing consistent barcodes for item numbers in the food industry.

GS1 runs autonomous national branches in many countries like GS1 Germany GmbH, situated in Cologne. GS1's international headquarter is based in Brussels.

GUDID and EUDAMED:
The central UDI databases

The center of the American UDI system is the "Global Unique Device Identification Database" (GUDID) that serves the registration and as a reference catalog for every device with an identifier. The EU's equivalent is the EUDAMED (European Database for Medical Devices) that serves the registration of all medical devices traded in European countries.

According to the UDI final specification, the manufacturer and labeler of each medical device labeled with a unique device identifier (UDI) must submit information concerning that device to the central directories. Such device identification information can be submitted either online via Web Interface or as a xml file.

The directory contains only the data of the device identifier (DI), the variable data of the UDI PI (Product Identifier) are exclusively on file in the code. However, the database contains production identifier flags to indicate which PI attribute(s) are on the device label.

Once a device is registered in the directory, both the public and all stakeholders engaged in the production and usage can access information contained in the directory. The GUDID and EUDAMED will be linked to databases around the world and will thus gain global influence.

→ Further information on the database and data transfer:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm

EUDAMED is scheduled to go into operation on 25 May 2022.

Endurance requirements of a UDI marking:
Resistance to multiple cleaning and passivation processes

A UDI-code must withstand strain and remain clearly legible throughout the entire product life cycle. This is to ensure traceability and patient safety. Only an appropriate marking technology is able to guarantee the mark's permanent resistance.

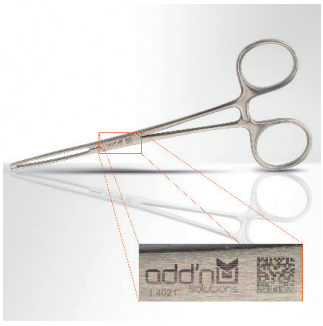
The European and US guidelines on UDI marking do not define detailed permanency timelines for laser marked UDIs, but include the general request for long-term stability of the marks in order to ensure seamless traceability. Manufacturers are therefore obliged to provide direct part marking which is compliant in any case.

With emphasis on reusable medical devices and instruments, the reliable stability of the direct mark against high alkaline sterilization and cleaning procedures is of crucial importance. Quality and corrosion resistance of the mark are crucial for a safe and continuous traceability of the product.

In cooperation with "add'n solutions GmbH" of Tuttlingen/Germany, FOBA executed a long-term study to examine the corrosion resistance of laser marks. The study showed that UDI codes which were marked with FOBA short pulse laser markers can resist at least 500 sterilization and cleaning cycles.

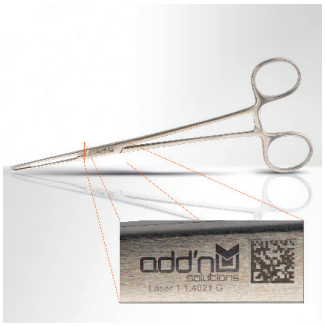
→ Find more information about FOBA's long term study about the durability of UDI marks on multiple use surgical instruments on the FOBA website: https://www.fobalaser.com/industry-solutions/medical-technology/

The "Application Case Study" on the subject is also available there for free download.

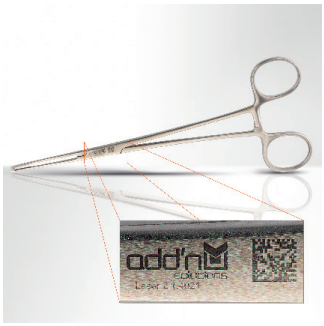


Laser marked without passivaion

Laser marked and passivated



Engraving after 500 reprocessing cycles



Annealing after 500 reprocessing cycles

The validation samples have been cleaned and autoclaved 500 times. The marks did not fade and are still reliably readable. After further sterilization cycles these results are not likely to change. The instruments themselves show the usual signs of use.

Secure and reliable product identification marking

Challenges and solutions for manufacturers and labelers

The requirements for the identification of medical devices are high. What is more, are the special requirements on the UDI labeling. Innovative marking systems not only solve these challenges but also contribute to an increase in production efficiency and improved product quality.

Requirements on marking systems

The requirements on the marking of medical devices are extremely stringent. **Marks have to be...**

- permanent and traceable,
- legible and readable,
- high in contrast,
- counterfeit-proof,
- sterilization-resistant,
- hygienic, clean, biocompatible
- and in the case of metals such as stainless, corrosion-resistant.

Due to the high demands on data quality of UDI codes, the requirements for code readability, and as such the marking quality, are especially precise. **UDI codes have to be readable free of error** – only then can the required unique, consistent, traceability be ensured. This assumes that the marking itself is error-free. The following points must be guaranteed:

- The correct product must be marked with the correct code (product conform).
- The mark must be correctly positioned.
- The code needs to legible over the long term (both plain text and machine readable).

Benefits of vision-assisted marking solutions

Many manufacturers apply **vision systems for code validation**. Aspects tested include; legibility, contrast, code positioning and the accuracy of the encoded data. Marking systems with machine-integrated imaging are particularly efficient. They save additional process and product handling steps outside the marking system, as marking quality and marked contents are verified directly in the marking station. Furthermore, the positioning of the mark turns out to be highly precise when aligned by the integrated camera system before the marking takes place.

As the device marking is often one of the last production steps, the direct marking must be applied reliably and safely. In this late manufacturing stage, product scrap due to incorrect markings is particularly costly. If marking errors can be corrected, the correction is time-consuming and cost-intensive. If they can't be corrected, the device itself has to be scrapped. Using pre- and post marking image-assisted validation and verification steps executed directly within the marking system itself, as well as automatic mark alignment, a machine-integrated vision system enables **stable marking processes** and **reliable, error-free marking results.** The advantages are obvious and include an increase in efficiency and product quality and a decrease in scrap.

UDI codes on a suction catheter (left) and on a balloon catheter (right)

Making the right choice:
Marking technology for product marking

One of the major challenges facing UDI is the implementation of the appropriate direct marking technology. The FDA does not specify which of the various available options should be used. Moreover, not every method is suitable for secure and UDI-compliant direct part marking; therefore choosing the best method to meet the requirements can be difficult and is crucial.

Above all, laser marking is ideally suited for the direct marking of medical devices with the Unique Device Identifier. It fulfills all the criteria relevant for safe product marking based on medical standards and UDI requirements.

Possible marking methods

- *Laser marking*
- *Inkjet (CIJ, Continuous Inkjet)*
- *Thermal inkjet (TIJ)*
- *Labels*
- *Dot peen*

Advantages of laser marking

Laser marking, in combination with a machine-integrated camera system, offers numerous advantages:

- → Process reliability, efficient and streamlined production:
  accurate and very repeatable marking using integrated camera system; stable marking processes; short processing times
- → Error-free marks:
  consistently high marking quality; accurate positioning of the correct content on the right product; less scrap
- → Reliable traceability:
  permanent, highly legible markings for safe product identification; OCV (Optical Character Verification) and code reading
- → Secure markings as required by medical standards:
  biocompatible, sterilization- and cleaning-resistant markings; contact-free, hygienic procedure

Laser marking machine with integrated vision system for inspection steps before and after marking.

Overview of potential marking methods

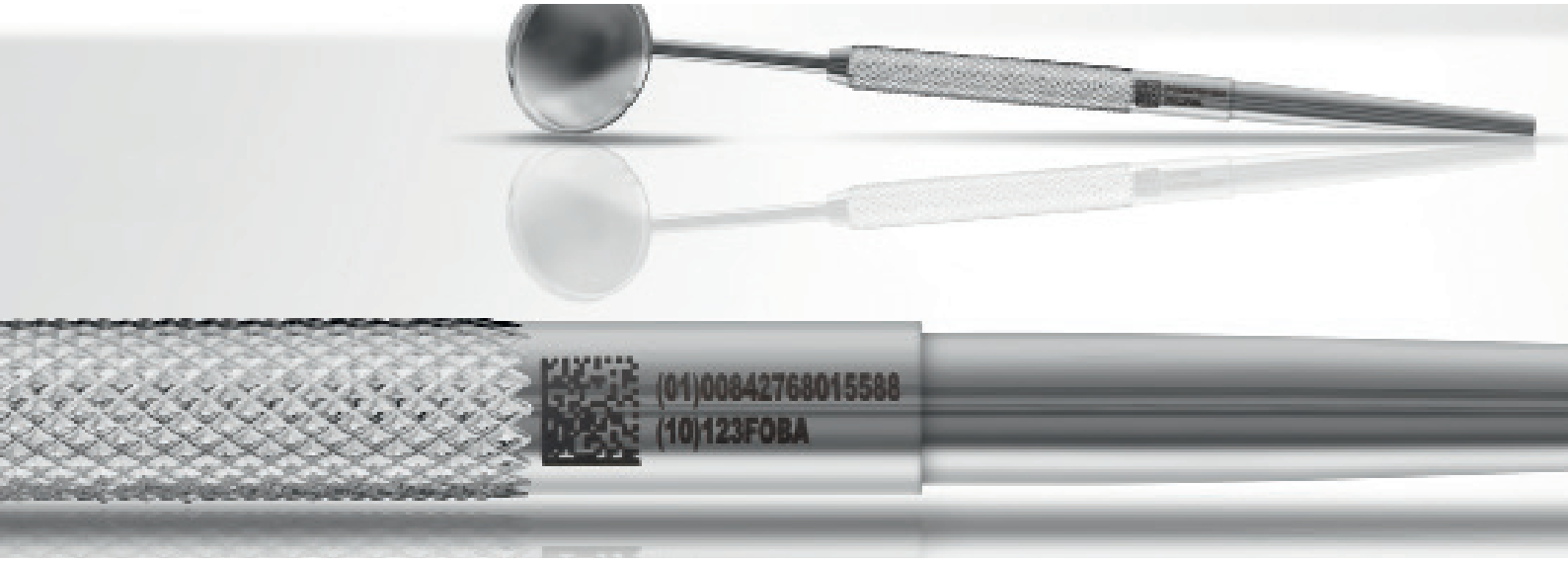
Marking characteristics					
Good readability/high quality	yes	sometimes	sometimes	yes	no
Machine readable	yes	yes	yes	yes	difficult
High contrast	yes	sometimes	sometimes	yes	no
Permanent and erosion resistant	yes	unclear	unclear	unclear	yes
Biocompatible	yes	unclear	unclear	unclear	yes
Marking does not give bacteria area to adhere to	yes	yes	yes	no	no
Resistant to acids, solvents, cleaning and sterilization	yes	risk	risk	risk	yes
Corrosion resistant	yes[1]	yes	yes	yes	risk
Passivation process resistant	yes[1]	yes	yes	test required	risk
Characteristics of the marking process					
Easy application of variable data, codes, series production	yes	yes	yes	yes	yes
Consumables (ink, paint, glue, etc.)	no	yes	yes	yes	no
Does not damage material	yes	yes	yes	yes	no
Low maintenance, low wear	yes	no	no	no	no
Adjustable marking size	yes[2]	limited	limited	yes	limited
Marking at rests	yes	no	no	yes	yes
Marking on the fly (MOTF)	yes	yes	yes	yes	no
Marking of uneven surfaces	yes	no	no	risk[3]	limited

The table shows standard marking methods with criteria relevant for the marking of medical devices with UDI codes.

[1]) if used correctly
[2]) from <1mm² to 400x400mm
[3]) label attachement method

FOBA®
Laser at your service

Laser marking of medical devices:
For reliable traceability, UDI compliance, product safety and quality



Laser marking is ideal for direct part marking (DPM) to meet the UDI standard and is ideally suited for serial applications with variable data and for mass production. The laser produces high-quality, permanent, readable markings on products and packaging and ensures the highest precision and process stability when combined with integrated vision systems.

→
The laser-based marking of medical products with the system, process and integrated vision solutions that FOBA offers provides many advantages over alternative methods. **We look forward to meeting with you for a live demonstration at our application lab or at your site, and are happy to provide you with free sample marking on your material.**
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