ADVENA LTD
EU UDI AND BUDI
A GUIDANCE DOCUMENT

CONTENTS

WHAT'S THE DIFFERENCE BETWEEN BASIC UDI-DI AND UDI-DI?

We must agree, the terminology used doesn't help! However, the Basic UDI-DI is primary alphanumeric identifier of a group of devices with the same intended purpose, classification, essential design and manufacturing characteristics, which does not appear on the labelling. Think of this as the "root" identifier.

On the other hand, the UDI-DI is a numeric identifier which refers to a specific product. Therefore, investigating a UDI-DI will lead you to one particular device variant, whilst a Basic UDI-DI may lead you to many UDI-DI.

Find out more on each of these in the below guidance.

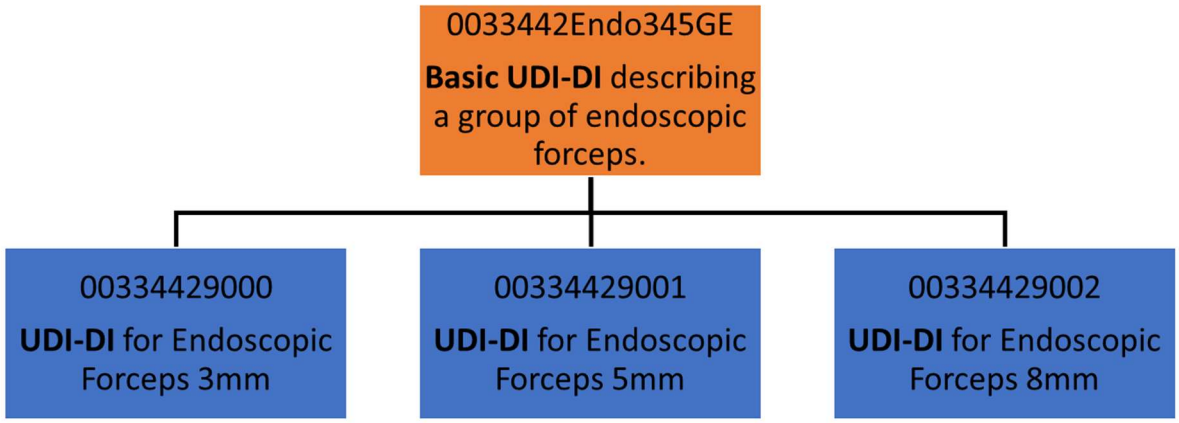


Image is not based on any particular UDI-issuing entity standards.

EU UNIQUE DEVICE IDENTIFIER (UDI)

Both the EU Medical Device Regulation 2017/745 (MDR) and the EU IVD Regulation 2017/746 (IVDR) now require that all devices being placed on the market in accordance with these Regulations will need to be assigned a Unique Device Identifier (UDI) in order to facilitate product identification and traceability on the EU market. This will be a monumental task for many device manufacturers, especially those with a vast list of products and variants. The following article is intended to provide an extensive look into the requirements of the EU UDI system and provide guidance on how you may assign these codes.

Definition and Anatomy

The Regulations define the UDI as "*a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market*" (MDR/IVDR Article 2(15)). The legislation

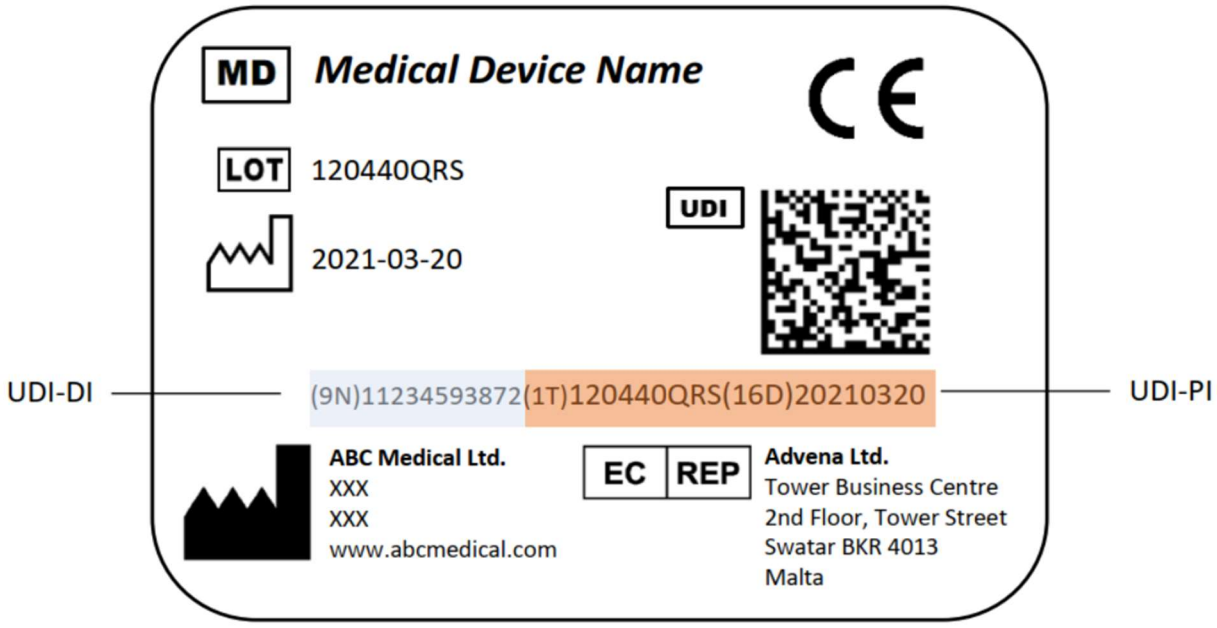
goes on to clarify that the word ‘unique’ does not imply serialization of individual units, which means that it is possible for two products to be carrying the same UDI.

The UDI is made up of two parts:

- -DI: Device Identifier.
- -PI: Production Identifier.

UDI-DI: This portion of the UDI is both specific to the manufacturer and device-group. This is considered to be the “access-key” to the UDI database information. Each product variant will have a different UDI-DI, and can be thought of as the product or catalogue number. A unique UDI-DI shall be assigned to each level of device packaging i.e. the various levels of packaging containing a fixed quantity of devices (e.g. carton or case); this does not include the shipping container.

UDI-PI: This shall identify the unit of device production and may include the serial number, the lot number, software identification and manufacturing / expiry date. This tracks the specific production series. If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If the label indicates a date of manufacture, this does not need to appear on the UDI-PI unless the expiry date is not indicated.



How do I assign a UDI to my device?

The first step should be to make a list of all the devices, variants, and packaging levels for which you will require a UDI. Each list entry should have a description of that item.

Choose one of the UDI-issuing entities designated by the EU Commission. Currently, the following entities have been designated to issue UDI for the EU: GS1, HIBCC and ICCBBA. Each entity has specific standards which must be followed to generate the UDI; in fact, the format of each of these entities will differ.

Once you have signed up with one of these entities, you should be provided with your own specific unique prefix which will identify you as the owner of that UDI. Using the standards or instructions provided by one of the issuing entities, you may then generate the UDI-DI and -PI for your devices.

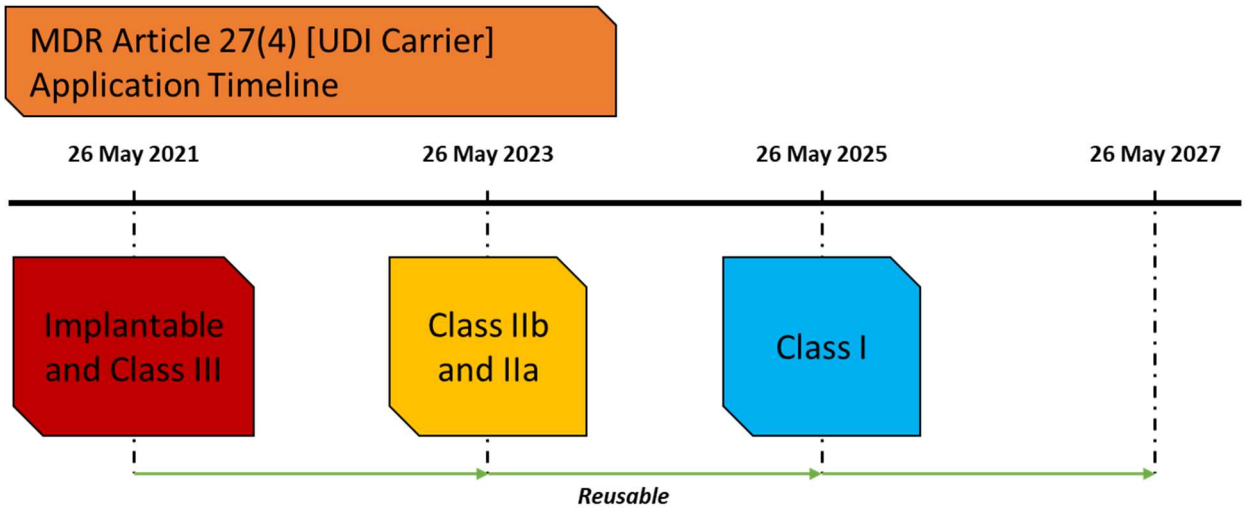
UDI Carrier

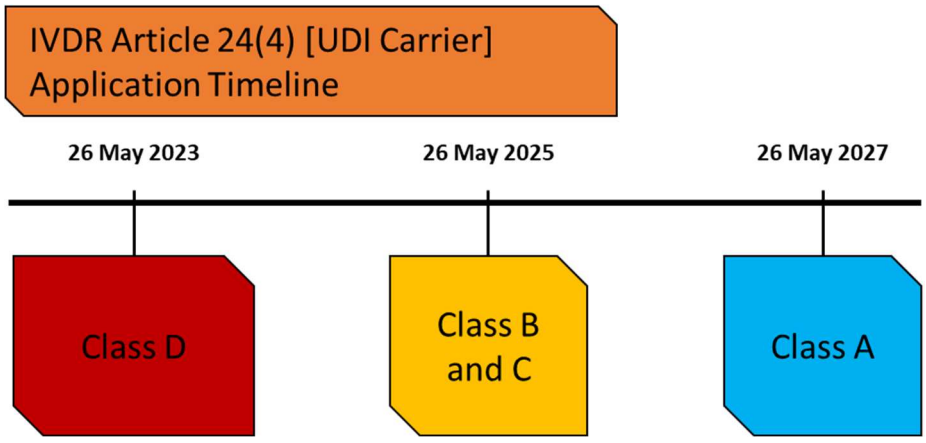
The UDI Carrier refers to the means by which the UDI is conveyed by using the Automatic Identification and Data Capture (AIDC) and Human Readable Interpretation (HRI), when applicable. The AIDC is the technology being used to automatically capture data e.g. barcodes, smart cards, biometrics, or RFID. On the other hand, the HRI is the legible characters encoded within the UDI Carrier. In the above example, the QR code is considered to be the AIDC, and the code beneath it the HRI. Together, they form the UDI Carrier.

The UDI Carrier shall be placed on the label or on the device itself and on all higher levels of device packaging. If there is a lack of space on the unit packaging, the Carrier may be shown on the higher packaging levels. In circumstances of limited space, the AIDC shall be shown in preference to the HRI for most cases. However, in the event the device is intended to be used in a care home setting or outside healthcare facilities, the HRI shall appear on the label even if there is no space for the AIDC.

Transitional Provisions

Article 123 of the MDR and Article 113 of the IVDR set transitional provisions for the inclusion of a UDI Carrier on the device labelling, as below. This means that by the dates indicated below the corresponding devices will need to show the UDI Carrier on the device labelling.





Device Changes

In some cases, changes made to the product may result in a new UDI-DI to ensure that the UDI is traceable to a specific product. If that product has changed, then it is reasonable to understand that the UDI-DI should also be changed. The Regulation is clear that in the event of the following changes to the product, the UDI-DI shall be updated (MDR Annex VI Part C (3.9)):

(a) Name or trade name.
(b) Device version or model.
(c) Labelled as single use.
(d) Packaged sterile.
(e) Need for sterilization before use.
(f) Quantity of devices provided in a package.
(g) Critical warnings or contra-indications.

Failure to do so may lead to the misidentification of the device. It is also crucial that manufacturers which are repackaging or relabeling devices with their own label retain a record of the original UDI. The AIDC shall be clearly identified on the label using the UDI symbol, as display in ISO 15223-1.

Rules for Specific Cases / Types of Devices

Single Use	For Class I and Class IIa single use devices packaged and labelled individually, the UDI Carrier does not need to be provided on the unit packaging label, but can be placed on the higher level e.g. carton. However, if the healthcare worker is not expected to have access to the higher packaging levels, then the UDI Carrier shall be placed on each individual product. Such as case would be in home healthcare settings.
Retail Point Products	For devices specifically intended to be provided for retail point of sale, the UDI-PI in AIDC does not need to be shown on the point of sale packaging.
Reusable	Such devices must indicate the UDI Carrier on the device itself and shall be permanent and legible after every process for their intended lifetime. This shall not apply in cases where: (a) any type of direct marking would interfere with the safety or performance of the device. (b) the device cannot be directly marked because it is not technologically feasible.
Assembled Devices	If a device needs to be assembled prior to being used, it is acceptable that the UDI Carrier be shown on one part of the device.
Implantable Devices	The UDI Carrier shall be shown on the unit packaging. For active implantable devices, the -PI portion shall contain the serial number. For other implantable devices, the serial number or lot number shall be indicated within the -PI.
Article 22	The natural or legal person responsible for the Article 22 system or procedure pack shall identify the system with a UDI. All device contents shall have a UDI on the device or their packaging with the exception of widely used single use disposable devices or devices exempted elsewhere in the regulation. The system or procedure pack shall be affixed with a UDI Carrier on the outside of the packaging.
Configurable	A UDI shall be assigned to the configurable device in its entirety, rather than to each component, with each UDI-DI being provided for each group of configurations, rather than for all possible configurations. However, the -PI shall be assigned for each configurable device, and the UDI Carrier shall be affixed to that part which is most unlikely to change.
Device Components	For devices made up from multiple components which are made available for commercial sale on their own shall have their own UDI.
Custom-Made and Performance Study / Investigation Device	Custom-Made devices, and devices intended for performance study or clinical investigation shall not have a UDI assigned to them.

Software

Software which is being commercially made available on its own and which is a device in itself will need to be assigned a UDI at the system level. The identification of software is considered to be a manufacturer control mechanism and is thus indicated within the -PI portion of the UDI. A new UDI-DI will be required whenever there are any of the following changes:

(a) the original performance;
(b) the safety or the intended use of the software;
(c) interpretation of data.

In the event of minor software updates, only the UDI-PI will need to be updated e.g. bug fixes, usability enhancements.

In cases where software is delivered by physical means, the UDI shall be displayed on each packaging level with AIDC and HRI. Furthermore, the UDI shall be displayed on the start-up/loading screen, about page, or other easily accessible page. If the software lacks a user interface, it must still be capable of transmitting the UDI through an API.

In electronic displays of the software, only the HRI will need to be shown. Furthermore, HRI format of the UDI for the software shall include the application identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

EU BASIC UDI-DI

In accordance with the new EU Regulations, the Medical Device Regulation 2017/745 (MDR) and the EU IVD Regulation 2017/746 (IVDR), manufacturers must assign a Basic UDI-DI (BUDI) to each of their devices (apart from custom-made devices). The Basic UDI-DI is an alphanumeric code assigned by the manufacturer which indicates a particular device group and is defined as:

the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Unlike the UDI Carrier, the BUDI is not displayed on the device, its labelling, or packaging, however, it will be indicated within the technical documentation, applicable certificates, and the Declaration of Conformity as a minimum.

A UDI-DI can only be associated with one Basic UDI-DI; thus, in Eudamed multiple UDI-DI registrations will be linked to a single Basic UDI-DI.

How do I assign the Basic UDI-DI?

The first step will be to split up your devices into different groups which will then be assigned a BUDI. The Regulation does not provide any specific guidance as to how this should be done, however, MDCG 2018-1 provides a hint that the BUDI is *intended to connect devices with same intended purpose, risk classification and essential design and manufacturing characteristics*. To get more information on how to group devices under a different BUDI, we may also look at the structure of Eudamed registrations.

Based on this guidance and the Basic UDI-DI Registration structure on Eudamed, we can recommend the following scheme for hierarchy for grouping your devices:

Level 1: Intended Purpose

Only devices with the same intended purpose shall be listed under a single Basic UDI-DI. This includes a consideration of indications, contra-indications, target users and target patients.

Level 2: Classification

Devices with different classifications shall be separated into a different Basic UDI-DI.

Level 3: Design Characteristics

The design of devices under a single BUDI grouping should have the same essential design characteristics. One example is when a product with the same intended use and classification can be provided active or not active (e.g. hot vs cold endoscopic instruments); these should have two separate BUDIs. Another example may be one in which a variant has a measuring function.

Level 4: Manufacturing Characteristics

Devices with different manufacturing characteristics shall be assigned a different BUDI. In some cases, the same device may be provided as sterile and non-sterile; these should have separate BUDIs.

Until more formal guidance is released, we recommend the use of MedTech Europe's guidance document for assigning Basic UDI-DI which is very comprehensive.

Basic UDI-DI Anatomy and Validation

The BUDI is typically formed from 3 main elements: Company Prefix, User-Inputted Alphanumeric Code, Check Characters.

GS1

GS1 refer to the BUDI as the Global Model Number (GMN), which is structured using the GS1 Company Prefix (acquired upon registering with GS1), the user-inputted alphanumeric code, and automatically generated check characters:

You may generate/validate the GMN using the resource at the following link: https://www.gs1.org/services/check-character-calculator

HIBCC

The HIBCC Basic UDI-DI is generated using the organisation's Labeler Identification Code (LIC) (acquired upon signing up with HIBCC), and automatically generated check characters. HIBCC BUDI typically contain a '++' prefix, e.g. ++A999MODELIDENTIFIER11S8.

You may generate/validate the HIBCC BUDI using the resource at the following link: https://www.hibcc.org/basic-udi-di-generator/

ICCBBA

At the time of writing of this article, there is generator for ICCBBA BUDI. However, you may find more information on how to generate it at the following link: https://ec.europa.eu/docsroom/documents/38567?locale=en

ICCBBA are 18 characters long, with two of these acting as the 'checksum'.