UDI Guideline for Identifying Medical Devices

February 2021

medi. I feel better.

As a manufacturer and distributor of medical devices, medi is obliged to fulfil the legal requirements stipulated within the Medical Device Regulation (MDR). One requirement incumbent upon medi is that it must label its medical devices and render them traceable in accordance with the MDR.

The requirements are defined precisely via the Unique Device Identification (UDI) guideline.

Therefore, we request that you comply with the following guideline on the UDI requirements.

Terms and Abbreviations

Medical Device (Article 2, no. 1 MDR)
'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Medical Device Regulation (MDR)
The MDR is a European Regulation which becomes binding in it's entirety as of 26 May 2021.
It places new legal requirements on all manufacturers of medical devices.
As a manufacturer and distributor of medical devices in risk class I, medi must also fulfil these new requirements. The extended information on labelling medical devices forms an important component of the regulation.
Further information: MDR (EU) 2017 / 745, Articles 10-14

Unique Device Identification (UDI)
UDI is a system for labelling medical devices and identifying them within the value-added chain. Manufacturers of medical devices are obliged to apply the standardised UDI information and symbols to the labels (product label and box label) in addition to the pre-existing requirements.
Further information: MDR (EU) 2017 / 745, Article 27 and Annex VI, Part C

Global Trade Item Number (GTIN)
The GTIN identifies the manufacturer and contains the article number of the product. The EAN number can be used for this purpose. This number comprises the code for the packaging unit and the EAN number.

Packaging unit
Packaging levels means the various levels of device packaging that contain a defined quantity of devices (packaging unit), such as a carton or case (MDR, Annex VI, Part C).

EAN Number
This is the old term for the Global Trade Item Number. The acronym stands for European Article Number. The EAN number is a means of unique device identification that is recognized throughout Europe, but the GTIN covers the entire globe.

Article number
Article numbers are used to identify different products from a single manufacturer (EN ISO 15223-1).

Use-by date
Date after which the product can no longer be used by patients. Those dates must be stored in documents of proof (EN ISO 15223-1).
Terms that are used as synonyms by medi (e.g. sell-by date) are also included under the terms “shelf life” and “use by”. The use-by date comprises both the storage duration and the maximum period that the item can be used for.

Manufacture date
Date of manufacture. This is the basis for calculating the use-by date (EN ISO 15223-1).

Lot number
Identifies a defined quantity of devices of an article. The lot number enables traceability throughout the added value chain within the medical sector.

Serial number
Uniquely identifies a specific product. This number is not necessarily mandatory if a lot number is present.

UDI Code
The GTIN, use-by date, manufacture date, lot number, and if required the serial number must be encrypted in one international standardised code, as a minimum.

Traceability
Means that the product’s source and where it was subsequently sold can be traced. For manufacturers, this means that traceability must be implemented right from the beginning (where was each individual yarn introduced) to the end (who was the product directly given to). Distributors must also ensure the relevant level of traceability (according to Article 25 MDR).

Series product
Is an industrially manufactured and reproducible product.

Special series
Designates an industrially manufactured and reproducible series product that is produced in smaller quantities (n is larger or equal to 1).

Made-to-measure devices
Is a product manufactured in series, based on individual patient dimensions, and is thus intended for one individual patient. Labelling of made-to-measure articles is depicted in a measurement guide.

Specific wish
In medi's definition, a specific wish is a serial product or a special series that fulfils a specific wish of an individual patient. This is not a custom-made device in accordance with MDR Article 2 Item (3); it is solely an adjustment which is made to a serial product.

MDR Medical Device Regulation
MD Medical Device
UDI Unique Device Identifier
GTIN Global Trade Item Number
CE CE marking
ERP Enterprise Resource Planning System
D Day
M Month
Y Year
Q Quarter

Procedure and Responsibilities

The subject of UDI is relevant for the following departments at medi:

IT	Batch traceability, master data management, maintenance of the Eudamed database
QA	Incoming goods checks, complaints
Purchasing	Supplier management incl. purchasing and supplier agreements
Production	Printing the data on the individual products
R&D	Establishing shelf lives
QM	Monitoring fulfilment of MDR requirements
Sales	Traceability, logistical monitoring activities
PM	Establishing labels and product information
CC	Feedback from market
MSMD	Logistics development incl. shelf lives and sell-off periods

1. General Information about MDR & UDI

Implementation of the Medical Device Regulation
As manufacturer of medical devices, we are required to comply with the stringent legal requirements of the new Medical Device Regulation (MDR), the latest European Regulation on Medical Devices which will apply as of May 26th, 2021.

The central objective of the MDR is to ensure the highest possible level of patient safety thanks to high-quality medical devices, which requires the supervision of supply chains between manufacturers and suppliers. With this in mind, we establish common definitions and points in line with the provisions of the MDR which will provide a framework for future collaboration along the supply chain.

The MDR imposes clear responsibilities on manufacturers, in particular with regards to liability for products placed on the market.

More information : MDR (EU) 2017/745, Article 10-14
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

Implementation of Unique Device Identification (UDI) as part of the MDR
The Unique Device Identification (UDI) is a system used to mark and identify medical devices within the healthcare supply chain. The IMDRF (International Medical Device Regulators Forum), the United States Food and Drug Administration (FDA) and the European Commission are aiming for a globally harmonized and consistent approach to increase patient safety and help optimize patient care by proposing a harmonized legislation for UDI, using global standards. Manufactures are obliged to provide standardized UDI information and symbols on labels (textile label and packaging label) in addition to the already applying regulations.

Therefore, medi has to consider data of the original manufacturer for its trading goods. After May 26th, 2021 only products meeting those requirements can be placed in the market.

More information: MDR (EU) 2017/745, Article 27 and Annex VI, Part C
FAQ: https://ec.europa.eu/docsroom/documents/36664

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2. Selling Off products Without UDI Data

According to MDR medical devices with old labels can be sold by retailers (also Groups and Distributors) within the EU until May 26th 2025 in case the expiry dates are not exceeded. This means that all products that currently have no expiry date will expire in 2025. This gives all Groups within the EU enough time to sell current stock.

Please note: It might be that some Groups and Distributors have stricter local legislation with the EU or in NON-EU-countries.

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3. Definitions of the medi UDI Data on Labels

Series products & special series

Date of manufacture
The point at which the last stage of manufacturing is completed defines the date of manufacture, based on the month. The date of manufacture is then set as the first month of the quarter (e.g. 2020-01, 2020-04, 2020-07, 2020-10).

Use-by date
Calculated based on the date of manufacture. The use-by dates are recorded as follows in the product master data in the ERP system:
42 months: Elastic products (stockings and bandages) or adhesives (footcare)
60 months: Hospitals
60 months: Non-elastic products (braces):

Lot number
Changes each quarter (e.g. 202001, 202002, 202003, 202004)

EAN Number
Is stored for the article in the product master data in the ERP system.
Made-to-measure & specific wish
Made-to-measure & specific wish

Date of manufacture
Derived from the date of order entry, on a monthly basis.

Use-by date
Calculated based on the date of manufacture. The use-by dates are stored as 7 months in the product master data in the ERP system:

LOT Number
Is the unique number for the article.

EAN Number
An EAN number is recorded for made-to-measure articles. This is based on the made-to-measure article number. For specific wish articles, the EAN number of the basic series / special series article is used.

Set articles
If an article consists of several parts or articles, then a new lot number, based on the order number, is generated when the complete article is packaged. The shortest durability from the parts will be adopted for the medical device. Parts may be medical devices or non-medical devices (e.g. circaid). If medi receives pre-packaged sets (e.g. circaid from the USA), then these will be treated like normal articles. This means that the overall lot number for the set will be recorded by the incoming goods department.

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4. Data Formats

UDI Code
The common standard from eurocom e.V. states that the UDI code must be presented on the relevant product packaging in the form of a data matrix barcode. 6 mm x 6 mm has been defined as the minimum size for this two-dimensional code. In general, the GS1 standard has been established as the basic coding system for the UDI structure for the present minimum standard.

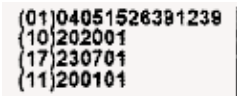
	Field	Fix or variable length
DI	(1)GTIN	Fix 14
Charge	(10)Lot	Variable 1...20
Serial number	(21)SN	Variable 1...20
Expiration date	(17)YYMMDD	Fix 6
Production date	(11)YYMMDD	Fix 6
Optional fields are possible		

The relevant content is distinguished with the following application identifiers in HRI (Human Readable Interpretation) code:

Potential application identifiers:
(01) GTIN of the trading unit (EAN number)
(11) Production date
(17) Expiration date / use-by date
(10) Batch / lot number
(21) Serial number
(240) Additional product identification (e.g. internal article code)
(400) Customer purchase order number

Configuration of the GTIN: Packaged unit + EAN number

Exemplary medi code



Data formats on box labels
- durability (same as "use by"): YYYY-MM
- Manufacture date: YYYY-MM
- Lot number for series / special series: YYYYQQ
- Lot number for made-to-measure / special article (specific wish): ZZZZZZZZZZ = made-to-measure number

Infor LN ERP file format for incoming goods recording
- Date of manufacture: YYYYMMDD
- Batch / lot: YYYYQQ
- Use-by date: DD.MM.YYYY

inconso file format
Use-by date = DD.MM.YYYY

Batch made in-house
Batch = date of manufacture + batch = YYYYMM01YYYYQQ
(first month in quarter)

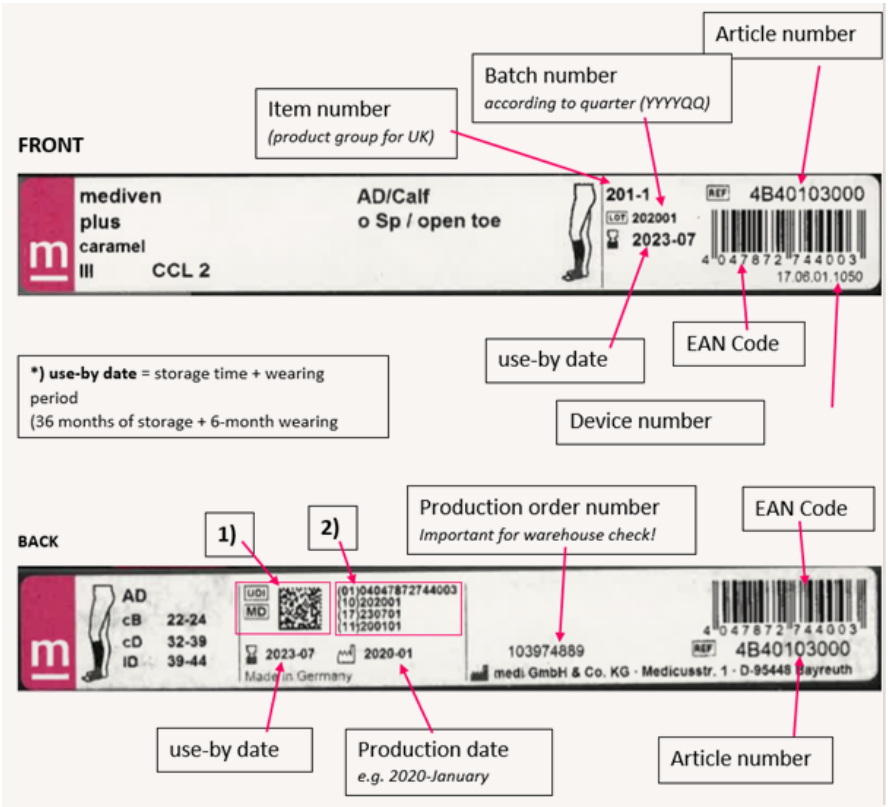
Batch made externally
Batch = date of manufacture + batch supplier = YYYYMMDDbatchsupplier

5. Symbols for UDI data on Box Labels

The UDI symbols are shown and explained in the eurocom document “Medical Device Symbols & Their Meanings” [Medizinprodukte Symbole & ihre Bedeutung]. Refer to the site of the eurocom e.V. association (www.eurocom-info.de)
medi shows the following symbols on the box labels:

- Date of date
- use-by date
- Serial number, if necessary
- Article number
- Manufacturer
- MD
- UDI
- LOT
- CE
- Number of uses minus 1
- Cannot be exchanged

Example label



In 1)

- UDI = Unique Device Identification
- MD = Medical Device
- The QR code contains the UDI data that are shown alongside in plain text.

In 2)

- (01) = EAN code
- (10) = Batch number
- (17) = Expiration date
- (11) = Production date

6. Information on Country of Origin on Label

For medi products whose country of origin is Germany, “Made in Germany” will be stated on the label.

If the country of origin is another country, no manufacturing country will be stated.

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7. Printing Box Labels

The layout for the box labels is produced using the nice label system and transferred to medi label. The systems pull the product master data defined in the layout from the ERP system. The UDI data are generated/adopted as follows, depending on the process (see 4.14):

- Generated automatically within medi label, based on the described medi logic. For reprints, manual inputting of UDI data is possible (e.g. for processing returns).
- Existing UDI data will be adopted by medi label from the ERP system / inconso (e.g. for trading goods).

The specific labels are stored in the relevant manufacturing specifications for the article.

Groups with „medi label“ can reprint the new “UDI labels”. Please see the instructions in the Appendix for details

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8. Traceability for medi BT

Traceability within medi
Traceability within medi is described in work instructions AA_24 and AA_25.

Traceability for customer / group / distributor
When processing an order, it is assured that the UDI data for the dispatched products are saved on the customer order. Thus, traceability showing which lot number has been sent to who is enabled (see 4.14).

9. Traceability in the medi Groups

MDR and ISO 13485 requires a traceability for all medical products throughout the supply chain (used raw material to distribution to economic operators, healthcare professionals or health institutions). The internal traceability for the products will be provided by medi Bayreuth – also in cooperation with our suppliers. medi Bayreuth will also know which LOT-number has been sent to which customer or Group. All Groups within the EU also have to track which LOT-number has been sent to which customer. This is not necessary if the customer is the end user (patient) of the product.
The need for traceability might also effect your stock keeping and your local efforts for order handling.

NOTE:
- For Groups within the EU it's mandatory due to MDR
- For Groups outside the EU this is mandatory due to ISO 13485

For Groups using the medi ERP-System or inconso a technical solution as described in the picture below has been implemented
- All articels must be scanned individually
- 2D scanners are needed in order to read the data matrix code

10. Sourcing

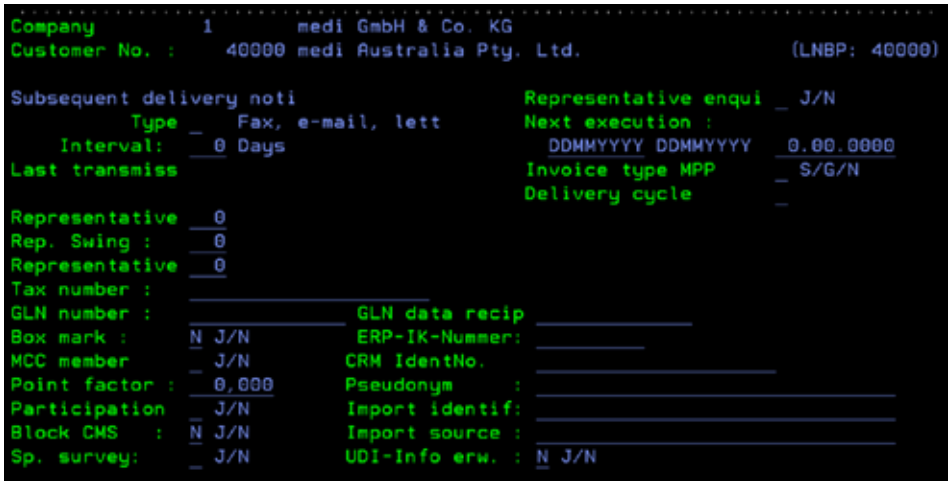
medi Bayreuth will secure UDI compliant medical devices for all medi products. Of course, medi Bayreuth is also in contact with partners like maxis, FGP, medi USA, handicap, hema and dekumed.

Medical devices which are sourced by the EU-Groups also need to be UDI compliant. The responsibility that the products meet the new regulations are within the groups.
If a group is the supplier, the manufacturer has to take care of the right labeling. Nevertheless, the groups need to secure traceability if the products are shipped to "non-end-users".
If a group is the manufacturer, the groups need to ensure the correct labeling including the traceability if the products are shipped to "non-end-users".

For more details please check the Sourcing Policy (VA_128_e)

11. Shipping documents / invoices

Whether or not the UDI data of lot number, date of manufacture and use by date are printed on shipping documents, invoices and packing lists is controlled via the master data field “UDI info requested” in the customer base. This applies for all documents, regardless of whether they are dispatched to the main address, dispatch address or direct address. This is slated to be introduced in May 2021 for shipping documents and invoices produced by medi Bayreuth. Groups which are connected to the medi ERP, have purged their warehouses and only have articles labelled with the new UDI labels can activate this function for their customers themselves. medi Bayreuth recommends that the function is only activated when this is legally required and/or if the customer explicitly requests this, as it does influence system performance.



NOTE:

- For Groups within the EU it‘s mandatory due to MDR
- For Groups outside the EU this is mandatory due to ISO 13485

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12. Rules for dispatch

Warehouse deliveries to Groups and Distributors:
minimum expiry time + 12 months for shipping and storage

In most cases the minimum expiry time is 12 months. Therefore, the products will be shipped with a minimum of 24 months of remaining product life (12+12); a few number of products (like maxis) have only 6 months as minimum expiry time (6+12); Exceptions are for example customer made products

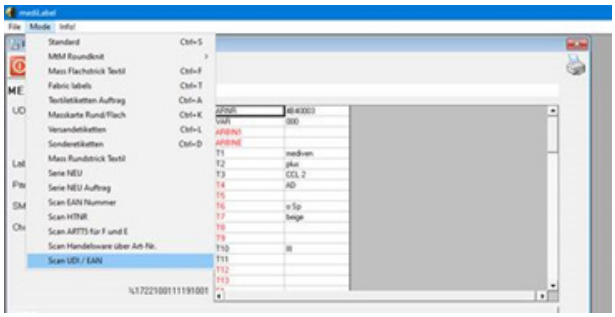
Direct shipments and backorders
Products which are shipped to customers directly or which are on backorder will be shipped with a minimum expiry time. In most cases this is 12 months.

Please note that in the mayority of cases the expiry time will be greater than 24 months

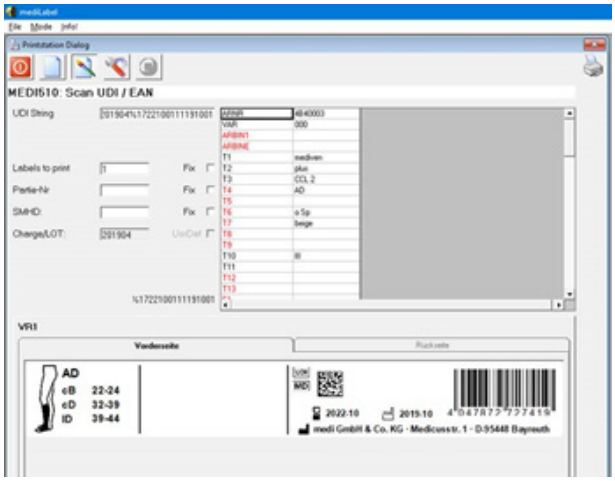
13. Appendix: Instructions medi label

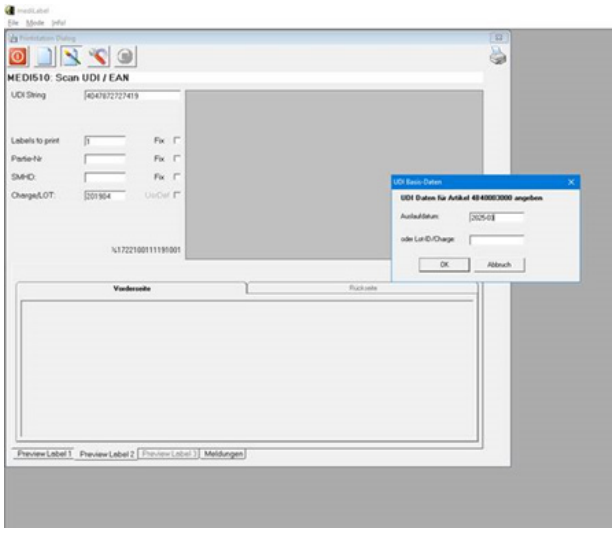
Mode: Re-Labeling
- You use this mode if you want to reprint labels
- You have two options: scan of new data matrix code (new labels) or EAN code (old labels)

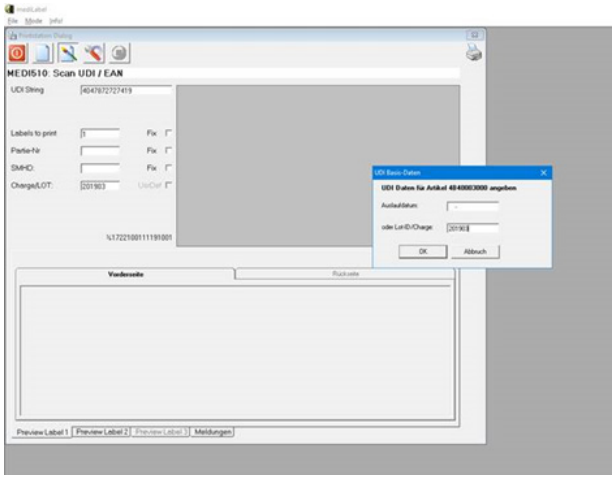
- Please choose the right mode



- Scan data matrix code or EAN-code
  - For data matrix code all relevant data is filled automatically
  - For EAN code you'll be asked to enter either LOT-number or expiry date







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We are available to answer your questions at any time.