S evice Regulation

Important information and recommendations regarding the European Medical Device Regulation (MDR)

What does the new Medical Device Regulation regulate?

The new European Medical Device Regulation defines the requirements regarding conformity assessment of medical devices. It combines the Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC) with the objective of implementing a higher standard and further increasing the focus on patient safety.

What is the reason behind the UDI (Unique Device Identification) system?

Under the Unique Device Identification (UDI) system, medical devices must bear a globally unique product number that is machine readable and included on the product and/or packaging, for example in a barcode. This code acts as a key for a UDI database (UDID) that contains various details about the products. Using the UDI improves the documentation and traceability of the materials used. The number enables information to be traced, such as the manufacturer of the medical device, product, manufacturing date and the production batch. Documentation on delivery notes or invoices is not required, as the products are frequently removed from storage and the batch number only needs to be documented when processing is carried out.

Implementing the MDR in accordance with VITA quality standards

1. VITA veneering and CAD/CAM materials

All VITA veneering and CAD/CAM materials bear a UDI-compliant Health International Bar Code (HIBC) that contains all the required information, either in digital form or in plain text. All units produced (e.g., bottles or blocks) are labeled with a batch number. The scannable barcode is provided on the primary packaging of the product.

2. VITA prosthetic teeth

Our tooth sets are also labeled with a UDI-compliant Health International Barcode. Every tooth set includes a verified and approved tooth batch that ensures correct batch traceability. As the risk class is low, batch identification is not required for each individual tooth.

What should be considered when using articles, especially denture teeth, without a lot number?

Set on which the teeth are mounted have a lot number. Individual denture teeth do not have LOT numbers. In order to ensure the required traceability, the lot number of the set must be recorded when the denture is manufactured.

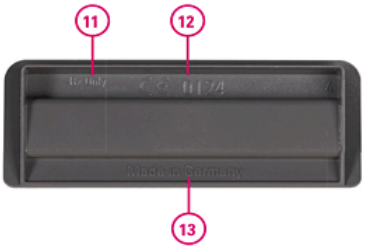
What do I have to enter in the documentation software if the VITA product has an unlimited shelf life?

If the field cannot be left blank, enter a fictional future date, e.g., 1/1/2071.

If I do not use documentation software, what information do I need to write down?

For the traceability of denture teeth, the designation (product name), shade, shape and lot number must be written down. For all other medical devices, the product number and lot number are sufficient for documentation.

Tooth set description VITAPAN EXCELL, VITA LINGOFORM, VITAPAN PLUS, VITAPAN, VITAPAN CUSPIFORM, VITA PHYSIODENS



1. Tooth shade
2. Tooth line
3. Tooth shape/size
4. LOT number
5. HIBC code

Identified HIBC code:

6. VITA manufacturer number
7. Product number
8. VITA packaging index
9. Manufacturing date
10. Manufacturer
11. Only to be used by technical staff
12. CE mark
13. Country of manufacture

Tooth set description VITAPAN SYNOFORM, LUMIN VACUUM, VITA PHYSIODENS

1. Tooth shade
2. Tooth line
3. Tooth shape/size
4. Manufacturer
5. HIBC code

Identified HIBC code:

6. VITA manufacturer number
7. Product number
8. VITA packaging index
9. LOT number
10. Control character for manufacturing date
11. Manufacturing date
12. Check number
13. Manufacturer address
14. CE mark

VITA tips and recommendations

Documentation options

To facilitate documentation, we recommend using a documentation software. Using a barcode reader, all UDI-compliant HIBC information on the medical devices can be scanned, transferred to the documentation soft-ware and saved.

Manual documentation of the product number and batch to ensure sufficient traceability, can also be carried out without a barcode reader. We do not attach adhesive labels, as this is not a sustainable solution and would require management of vast quantities of labels, given the large number of components.

Declarations of conformity

You can conveniently download and manage declarations of conformity in our MyVITA online portal.
Simply register at www.vita-zahnfabrik.com/MyVITA-Register

In the "Declarations of conformity" section, you can access the service "Automatic updates for your declarations of conformity." If requested, your selected VITA declarations of conformity are updated automatically. You will also be informed via email when a new version is available.

Download Customer information MDR