European Medical Device Regulation (MDR)

What are the changes for the dental practices?

The European Medical Device Regulation (MDR) has come into effect on 25 May 2017 and has replaced on 26 May 2021 the previously applicable Medical Devices Act (MPG) and its European predecessor, the Medical Device Directive (MDD). In this overview article, the editorial team highlights what will change for dental practices. The BDIZ EDI has been providing information about the MDR since 2019.

The MDR regulates the production and processing of medical devices. It is intended to ensure the safety, suitability and performance of medical devices and their supplies, as well as the health and necessary protection of patients, users and third parties. Compared to the MDD, the regulation provides for increased requirements for the marketing and surveillance of medical devices in the European Union.

Significant changes in dental practice will be:

- the development of a risk management system (Art. 10 Para. 2, Annex I No. 3).
- the extension of the storage obligations for documentation to at least 10 years and for implantable products to 15 years (Art. 10 Para. 5 MDR, Annex XIII No. 4)
- the designation of a responsible person (Safety Officer Art. 15)
- the batch traceability (Art. 25)
- the concrete recording of all substances remaining in the medical device, systematic recording of all batches and allocation to patient work
- the adjustments to the declarations of conformity (Art. 52 Para. 8, Annex XIII No. 1)
- the clinical evaluation and post-marketing clinical follow-up of medical devices (Art. 83, Annex XIV Part A and B)
- the incident recording and reporting system, post-marketing surveillance (Art. 83, Art 87 MDR)

Medical devices in the dental practice

Many different medical devices are used in dental practices and are subject to different requirements depending on their classification.

According to Art. 2 No. 1 MDR, "medical devices" are instruments, apparatuses, devices, software, an implant, reagents, materials or other articles which are intended for use in or on humans and which achieve their effect primarily by physical means (not by pharmacologically or immunologically active means).

"Accessory to a medical device" means, according to Art. 2 No. 2 MDR, an object which, although not a medical device per se, is intended by the manufacturer to be used together with one or more specific medical devices and specifically enables its/their use in accordance with its/their intended purpose(s) or is intended to specifically and directly support the medical function of the medical device(s) with regard to its/their intended purpose(s).

"Implantable medical device" means, in accordance with Article 2(5) of the MDR, a medical device, even if intended to be fully or partially resorbed, that is intended to be used "through a clinical intervention" to

- be introduced entirely into the human body, or
- replace an epithelial surface or the surface of the eye and remain there after the procedure.

An implantable product is also any product intended to be partially inserted into the human body by clinical intervention and to remain there for at least 30 days after the intervention.

Medical device classification

As in the past, medical devices are classified into classes I, IIa, IIb and III, considering their intended purpose and the associated risks. If the device in question is intended to be used in combination with another device, the classification rules are applied separately to each device. Classification is carried out in accordance with Annex VIII of the MDR.

Class IIa, IIb and III medical devices must bear – in addition to the CE marking – the number of the noti-

fied body that has carried out a conformity assessment procedure for the medical device in question. Class I medical devices are only required to bear the CE marking.

"CE conformity marking" or "CE marking" means a marking by which a manufacturer indicates that a device complies with the applicable requirements set forth in the MDR or in other Union legislation concerning the affixing of the relevant marking.

Except for custom-made or investigational devices, all medical devices bear a CE mark of conformity, Annex V of the MDR.

For the dental practice, the first important distinction is between mass-produced medical devices and custom-made devices.

Medical devices manufactured as standard

Most medical devices used in dental practices are mass-produced by third parties. The manufacturers of these medical devices classify them.

Customized dental products

According to Art. 2 No. 3 MDR, a "custom-made device" means a device that is specially made in accordance with a written prescription issued by a person authorized by his or her professional qualifications under national law to issue prescriptions, who is responsible for determining the exact design and characteristics of the device – which is intended for a single patient only – to meet exclusively the patient's individual condition and needs. The method of manufacture is not relevant. Restorations made using CAD/CAM are also a custom-made product.

Customized products are for example:
- fixed dentures
- removable dentures
- splints.

However, mass-produced products that must be adapted to meet the specific requirements of a professional user and products that are mass-produced by industrial processes in accordance with the written regulations of a person authorized to do so are not considered custom-made products.

Not customized products are, for example:
- ready-made teeth
- industrially produced attachment elements
- implant components.

Customized products are usually class I or class IIa medical devices. Only abutments are currently classified by some manufacturers as implantable medical devices, surgically invasive, in class IIb.

Risk management system

Annex I (No.3) MDR requires manufacturers to implement a risk management system. For dental practices that manufacture custom products, this means that an appropriate risk management system must be introduced and continuously documented.

A risk management system consists of:
- a risk management plan (risk management documents, the result of the initial risk analysis)
- a risk analyses (product groups, product life phases, risk minimization)
- a monitoring plan and safety report (product monitoring)

Note: It is true that denture repairs and extensions are not new productions. Nevertheless, documentation and traceability must be ensured regarding the materials that were newly introduced as part of the repair and extension.

Responsible person

Manufacturers – including dental practices where custom products are manufactured – must have at least one person in their organization with the necessary expertise in the field of medical devices who is responsible for ensuring compliance with the regulatory requirements.
The tasks of the person responsible for regulatory compliance clearly exceed the tasks of the previous safety officer for medical devices. Especially the system of recording and reporting of incidents and post-marketing surveillance is to be emphasized.

This responsibility can be assigned to the practice owner or to the dental technician in the practice's own laboratory. Micro and small enterprises, i.e. those that employ fewer than 50 people and whose annual turnover or annual balance sheet does not exceed €10 million, are not required to have a person responsible for regulatory compliance; however, they must have continuous and permanent access to such a person. This means that external service providers can fully assume the function of responsible persons for small and micro-enterprises.

Traceability

According to Art. 25 MDR, all economic operators of a medical device (manufacturer, authorized representative, importer, distributor) must ensure identification within the supply chains. For dental practices, this means working with distributors and importers as well as manufacturers or their authorized representatives to achieve an appropriate level of product traceability. Within the period of 10 years (15 years

for implantable devices) it must be possible to declare to the competent authority:

- From whom was which product obtained?
- To whom was which product supplied?

This requires not only a concrete recording of all materials which remain in the medical product, but also a system of batch traceability with allocation to the respective patient restoration.

Declaration of conformity

The previous documentation of the declaration of conformity for customized products must be adapted to the new requirements of the MDR. Thus – in addition to the name and address of the manufacturer – all manufacturing sites must be indicated. In addition, the retention period for the documentation has been increased from 5 to 10 years. For implantable medical products, a retention period of 15 years applies. Content requirements are also available online.

Monitoring the marketing placing of medical devices

Manufacturers – including dental practices that produce customized products – must plan, set up, document, apply, maintain and update a post-market surveillance system for each medical device.

For this purpose, according to Art. 84 and Art. 86 MDR, a

- post-marketing surveillance plan and a
- regularly updated report on safety are required.

According to Annex XIV, Parts A and B of the MDR, a clinical evaluation and a post-market clinical follow-up of the medical devices must also be carried out. The clinical evaluation should be planned, continuously performed and documented for each medical device. The post-market clinical follow-up should be a continuous update of the clinical evaluation. The methods and procedures for proactive collection and evaluation of clinical data should be described.

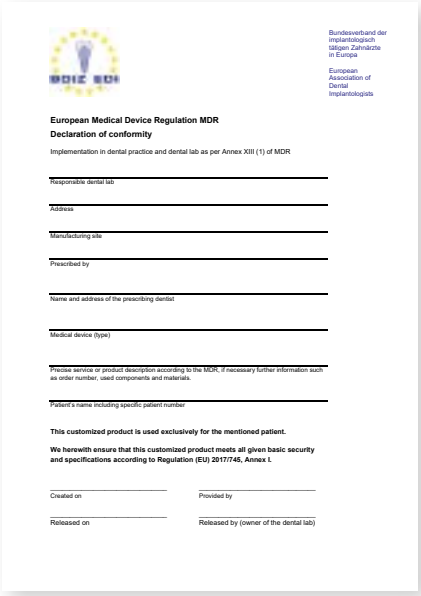
Incidents must be monitored and reported

The MDR requires a system of recording and reporting of incidents, post-market surveillance. The system for recording and reporting incidents, post-market surveillance specifies how

- incidents are recorded and evaluated,
- serious incidents are reported,
- if necessary, recalls are carried out or information on measures is provided.

The reporting deadline for serious incidents (corresponding to the previous reportable incident) has been reduced from 30 days to 15 days in accordance with Art. 87 (2) MDR.

In case of a serious risk to public health, a notification is required after 2 days at the latest after the manufacturer has become aware of it. In case of death or serious deterioration of health, notification is required after 10 days at the latest. *AWU*



Bundesverband der implantologisch tätigen Zahnärzte in Europa

European Association of Dental Implantologists

European Medical Device Regulation MDR
Declaration of conformity

Implementation in dental practice and dental lab as per Annex XIII (1) of MDR

Responsible dental lab

Address

Manufacturing site

Prescribed by

Name and address of the prescribing dentist

Medical device (type)

Precise service or product description according to the MDR, if necessary further information such as order number, used components and materials.

Patient's name including specific patient number

This customized product is used exclusively for the mentioned patient.

We herewith ensure that this customized product meets all given basic security and specifications according to Regulation (EU) 2017/745, Annex I.

Created on

Provided by

Released on

Released by (owner of the dental lab)

MDR forms online

As described in the article, the BDIZ EDI makes the necessary forms available on the www.bdizedi.org/en/website. The PDFs are interactive, meaning they can also be filled out electronically. For more Information, please contact us: office-munich@bdizedi.org

To download the form obove, please scan the QR code or visit: https://bdizedi.org/en/mdr-transitional-period-runs-out-on-may-26th/