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Dentistry - Guidance on the classification of dental devices and accessories

Médecine bucco-dentaire - Recommandations relatives
à la classification des dispositifs dentaires et
accessoires

Zahnheilkunde - Anleitung zur Klassifizierung von
Dentalprodukten und Zubehör

This Technical Report was approved by CEN on 21 February 2023. It has been drawn up by the Technical Committee CEN/TC 55.

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European foreword

This document (CEN/TR 12401:2025) has been prepared by Technical Committee CEN/TC 055 “Dentistry”, the secretariat of which is held by DIN.

This document will supersede CEN/TR 12401:2009.

The main changes compared to the previous edition are listed below:

- Updating of the Tables;
- Updating from the Council Directive 93/42/EEC (MDD) to the Regulation (EU) 2017/745 (MDR) and clarifying the intent of this technical report;
- Clarifying the intent of this technical report in regards to the MDCG 2021-24.

The responsible working group is CEN/TC 55/WG 3 “Classification” (secretariat: DIN), representing the dental trade and industry, the dental profession and notified bodies.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

Introduction

Dental products are marketed for long term, short-term and transient use in the mouth. A large number of items have been developed to assist in the treatment and prevention of oral diseases and the handling of dental materials. In contrast to pharmaceuticals (medicinal products), many dental materials are intended to perform as implanted devices in the oral cavity with a minimum of degradation and release of substances, i.e. their main action is to replace lost and defective teeth and oral tissue. Some materials contain elements that may initiate toxic or allergic responses. Other materials have additions of medicinal substances.

Many dental materials, instruments, equipment and disposables are covered by the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The Regulation also provides rules for the classification of medical devices based on risk and intended use. It is the manufacturer's responsibility to classify the product according to the rules of the Regulation.

It is important that the classification is acceptable to Notified Bodies (NB) and Competent Authorities (CA). The Regulation describes procedures for resolving any disputes over classification between manufacturers, Notified Bodies and Competent Authorities.

The Medical Device Coordination Group (MDCG) has prepared a document, MDCG 2021-24 "Guidance on classification of medical devices".

This document is not directly related to MDCG 2021-24 and MDCG has not been part of the drafting process. This document is providing an opinion on how specific medical devices in dentistry can be classified. It will, therefore, be of value to manufacturers in making decisions with regard to the likely classification of particular devices.

1 Scope

This document provides an opinion on the application of the classification rules in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices as they pertain to dental devices and accessories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 1942, *Dentistry - Vocabulary (ISO 1942)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 1942 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

4 Classification of dental devices and accessories

The list of dental devices and accessories given in Tables 1 to 5 is not exhaustive. The classification is based on the most commonly accepted form and intended use of the devices and accessories listed. If a manufacturer proposes another intended use, the classification of the product can be reconsidered.

Materials and other prefabricated devices that will be part of a custom-made device are included in this guidance document. Custom made devices are not. Some materials can be used both for long term and short-term custom-made devices. The intended purpose claimed by the manufacturer will then be decisive for the classification. In this document, the implementing rule 3.5 of the Regulation has been used for the proposed classification, i.e. “the strictest rules.....shall apply”.

This list is intended to be considered in conjunction with the Regulation 2017/745 EU [1] and MDCG 2021-24 “Guidance on classification of medical devices” [2] as prepared by the Medical Device Coordination Group (MDCG).

Possible classifications of dental devices and accessories are given in Tables 1 to 5.

5 Invasive devices

5.1 Basic overview

Table 1 — Invasive devices used in the oral cavity

Intended use	Rule	Class
Long term use (more than 30 days)		
Plastic materials for direct insertion	8	II A
metals		
polymers		
cements		