



**SLOVENSKI STANDARD**  
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**Zobozdravstvo - Napotki za razvrščanje zobozdravstvenih naprav in pripomočkov**

Dentistry - Guidance on the classification of dental devices and accessories

Zahnheilkunde - Anleitung zur Klassifizierung von Dentalprodukten und Zubehör

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

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TECHNISCHER REPORT

**FINAL DRAFT**  
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English Version

## 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 draft Technical Report is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/TC 55.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## European foreword

This document (FprCEN/TR 12401:2022) has been prepared by Technical Committee CEN/TC 055 "Dentistry", the secretariat of which is held by DIN.

This document is currently submitted to the Vote on TR.

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.

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## 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 intended to complement that guidance. It will, therefore, be of value to manufacturers in making decisions with regard to the likely classification of particular devices.

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## 1 Scope

This document provides guidance 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 may need to 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).

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
<b>Long term use (more than 30 days)</b>		
Plastic materials for direct insertion metals polymers cements	8	II A

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Intended use	Rule	Class
Cavity lining materials	8	II A
Dentine adhesives	8	II A
Pit and fissure sealants	5	II A
Protective film (long term)	5	II A
Pulp capping materials non medicated medicated	8 13	II A III
Endodontic filling materials sealers points retrograde root canal filling materials	8	II A
Luting materials water based cements eugenol based cements polymer based cements	8	II A
Materials for fixed prostheses and inlays metals ceramics and glass polymers	8	II A
Materials for removable prostheses and other intraoral appliances including maxillofacial prostheses metals ceramics polymers	5	II A
Endostabilizers / Transendodontic implants	8	II B
Prefabricated parts, surgically invasive, transient, short term or long term use (e.g. pins, posts, attachments)	6,7,8	II A
Orthodontic materials and devices, intraoral use metals ceramics polymers	5	II A
Dental implants metals ceramics and glass polymers carbon based calcium based	8	II B
Dental implants, biologically active coating	8	III



Intended use	Rule	Class
Bone substitutes	8	II B
non resorbable	8	III
resorbable		
Materials for guided tissue regeneration	8	II B
non resorbable	8	III
resorbable		
Osteo-synthesis devices	8	III
<b>Short term use (max. 30 days)</b>		
Protective films (varnish)	5	I
Protective films, medicated	13	III
NOTE 1 Films with a primary function of slow release of medicines are a medicinal product.		
Temporary filling materials	7	II A
Temporary crowns and bridges	7	II A
prefabricated		
materials for custom made temporary devices		
Short term relining and tissue conditioning materials	5	I
non medicated	13	III
medicated		
Surgical packs (dressings)	7	II A
Surgical packs, medicated	13	III
Suture material, non absorbable	7	II A
Suture material, absorbable/medicated	13	III
<b>Transient use (less than 60 min)</b>		
Syringe tips for delivery of dental materials	5	I
Materials for surface preparation (etch, prime)	6	II A
Bleaching agents for intra dental bleaching professional use only	6	II A
Impression materials	5	I
Rubber dam and accessories	5	I
Cotton rolls, gaze, etc.	5	I
Wedges	5	I
Waxes	5	I
Gingival retraction device	5	I
Gingival retraction device, medicated	13	III
NOTE 2 Astringents and haemostatic solutions are medicinal products.		
Matrix bands	5	I

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Intended use	Rule	Class
Impression trays	5	I
Endodontic absorbant points	6	II A
Polishing paste	5	I
Polishing paste, medicated	13	III
Polishing strips	5	I
Articulating, occlusion and bite registration devices	5	I
Radiographic devices	16	II A

Table 2 — Invasive devices used in the oral cavity by the patient

Intended use	Rule	Class
<b>Long term use (more than 30 days)</b>		
Cushions and relining materials	5	II A
<b>Short term use (max. 30 days)</b>		
Trays for gels	5	I
Temporary filling	6	II A
Denture adhesives, cushions and relining materials	5	I

## 5.2 Examples for invasive devices

Product description	Class	Rule	Comments
Applications syringes/cannulas	I IIa	Rule 5 Rule 6	Invasive (e.g. for impression materials) Surgically-invasive (e.g. for cements)
Amalgam	IIa	Rule 8	Placed in the teeth
Articulation and occlusion materials	I IIa	Rule 5 Rule 19	If nanomaterial is present
Bite registration materials	I IIa	Rule 5 Rule 19	if nanomaterial is present
Bleaching materials for tooth whitening	IIa	Rule 6 and Rule 7 Rule 19	Content of peroxide >6% If nanomaterial is present, potential for internal exposure of nanomaterials is negligible

Product description	Class	Rule	Comments
Drill sleeves, stop sleeves	I	Rule 5, first part of sentence	Products are used for transient use of X-ray verification of prosthetic requirements and for guiding surgical instruments. Invasive use in natural body openings.
Arcs, orthodontic	Ila	Rule 5, 3 <sup>rd</sup> Indent	Long-term use
Brackets	Ila	Rule 5	Long-term use
Calcium hydroxide, Calcium salicylate, Calcium sulfate	Ila	Rule 8	
Expansion screws	Ila	Rule 5, 3 <sup>rd</sup> Indent	Long-term use
Dental implants and abutments	Iib	Rule 8	Long-term use, not placed “in the teeth”, therefore not Class Ila
Dental implants, biological coated	III	Rule 8 3 <sup>rd</sup> Indent	If biological action is claimed
Desensitizer	I I	Rule 5 1 <sup>st</sup> Indent Rule 5 second Indent	For transient use For short-term use in the oral cavity
Wires, orthodontic (wires, orthodontic arcs for orthodontics)	Ila	Rule 5, 3 <sup>rd</sup> Indent	Long-term use
Excavator, dental	Ir	Rule 6	Surgical invasive instrument, reprocessable
Pit and fissure sealant	Ila	Rule 5 or Rule 8	
Filling materials (composite, glass-ionomer-cements, ceramic inlays, galvano inlays)	Ila Ila	Rule 8 Rule 19	if nanomaterial is present Potential for internal exposure of nanomaterials is negligible
Filling materials (temporary, provisional)	Ila	Rule 7 or 8	Depending on usage time
Attachments	Ila	Rule 8	Fixed, long-term use
Holding elements, orthodontic	Ila	Rule 5	Invasive product, used in the oral cavity
Handpieces and angled pieces (connected on motor)	Ila	Rule 9	
Bone Rongeur, gouge pliers	Ir	Rule 5	