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| <b>TNI</b> | <b>Stomatológia</b><br><b>Odporúčanie pre klasifikáciu stomatologických</b><br><b>pomôcok a príslušenstva</b> | <b>TNI</b><br><b>CEN/TR 12401</b><br><br>85 6040 |
|------------|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------|

Dentistry - Guidance on the classification of dental devices and accessories

Táto technická normalizačná informácia obsahuje anglickú verziu CEN/TR 12401:2025.  
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**CEN/TR 12401**

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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 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 COMMITTEE FOR STANDARDIZATION  
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**CEN/TR 12401:2025 (E)**

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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.

**CEN/TR 12401:2025 (E)****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 |
|-------------------------------------------------------------------------|------|-------|
| <b>Long term use (more than 30 days)</b>                                |      |       |
| Plastic materials for direct insertion<br>metals<br>polymers<br>cements | 8    | II A  |

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| <b>Intended use</b>                                                                                              | <b>Rule</b> | <b>Class</b> |
|------------------------------------------------------------------------------------------------------------------|-------------|--------------|
| 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                                                                                                    | 8           | II A         |
| medicated                                                                                                        | 13          | III          |
| Endodontic filling materials                                                                                     | 8           | II A         |
| sealers                                                                                                          |             |              |
| points                                                                                                           |             |              |
| retrograde root canal filling materials                                                                          |             |              |
| Luting materials                                                                                                 | 8           | II A         |
| water based cements                                                                                              |             |              |
| eugenol based cements                                                                                            |             |              |
| polymer based cements                                                                                            |             |              |
| Materials for fixed prostheses and inlays                                                                        | 8           | II A         |
| metals                                                                                                           |             |              |
| ceramics and glass                                                                                               |             |              |
| polymers                                                                                                         |             |              |
| Materials for removable prostheses and other intraoral appliances including maxillofacial prostheses             | 5           | II A         |
| metals                                                                                                           |             |              |
| ceramics                                                                                                         |             |              |
| polymers                                                                                                         |             |              |
| 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                                                                 | 5           | II A         |
| metals                                                                                                           |             |              |
| ceramics                                                                                                         |             |              |
| polymers                                                                                                         |             |              |
| Dental implants                                                                                                  | 8           | II B         |
| metals                                                                                                           |             |              |
| ceramics and glass                                                                                               |             |              |
| polymers                                                                                                         |             |              |
| carbon based                                                                                                     |             |              |
| calcium based                                                                                                    |             |              |
| Orthodontic implants                                                                                             | 8           | II B         |

| <b>Intended use</b>                                                                        | <b>Rule</b> | <b>Class</b> |
|--------------------------------------------------------------------------------------------|-------------|--------------|
| Dental implants, biologically active coating                                               | 8           | III          |
| Bone substitutes                                                                           |             |              |
| non resorbable                                                                             | 8           | II B         |
| resorbable                                                                                 | 8           | III          |
| Materials for guided tissue regeneration                                                   |             |              |
| non resorbable                                                                             | 8           | II B         |
| resorbable                                                                                 | 8           | III          |
| 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                                      |             |              |
| non medicated                                                                              | 5           | II A         |
| medicated                                                                                  | 13          | III          |
| Surgical packs (dressings)                                                                 | 7           | II A         |
| Surgical packs, medicated                                                                  | 13          | III          |
| Suture material, non absorbable                                                            | 7           | II A         |
| Suture material, absorbable/medicated                                                      | 13          | III          |
| Mandibular advancement devices for antisnoring and sleep apnoea, dental                    | 5           | I            |
| <b>Transient use (less than 60 min)</b>                                                    |             |              |
| Syringe tips for delivery of dental materials                                              | 5           | I            |
| Materials for surface preparation (prime)                                                  | 5           | II A         |
| Materials for surface preparation (etch)                                                   | 5           | I            |
| Impression material                                                                        | 5           | I            |
|                                                                                            | 19          | II A         |
| Rubber dam and accessories                                                                 | 5           | I            |
| Cotton rolls, gaze, etc.                                                                   | 5           | I            |
| Wedges                                                                                     | 5           | I            |
| Waxes                                                                                      | 5           | I            |



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| Intended use                                                         | Rule | Class |
|----------------------------------------------------------------------|------|-------|
| Gingival retraction device                                           | 5    | I     |
| Gingival retraction device, medicated                                | 13   | III   |
| NOTE 2 Astringents and haemostatic solutions are medicinal products. |      |       |
| Matrix bands                                                         | 5    | I     |
| Impression trays                                                     | 5    | I     |
| Endodontic absorbent 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                                                 | 17   | II A  |

**Table 2 — Invasive devices used in the oral cavity**

| 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  |

**5.2 Examples for invasive devices**

| Product description                      | Class | Rule                              | Comments                                                                                                                                                          |
|------------------------------------------|-------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Applications syringes/cannulas           | I     | Rule 5                            | Invasive (e.g. for impression materials)                                                                                                                          |
|                                          | IIa   | Rule 6                            | Surgically-invasive (e.g. for cements)                                                                                                                            |
| Amalgam                                  | IIa   | Rule 8                            | Placed in the teeth                                                                                                                                               |
| Articulation and occlusion materials     | I     | Rule 5                            | If nanomaterial is present                                                                                                                                        |
|                                          | IIa   | Rule 19                           |                                                                                                                                                                   |
| Bite registration materials              | I     | Rule 5                            | If nanomaterial is present                                                                                                                                        |
|                                          | IIa   | Rule 19                           |                                                                                                                                                                   |
| Drill sleeves, stop sleeves              | I     | Rule 5,<br>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. |
| Wires, arch wires and tubes, orthodontic | IIa   | Rule 5,<br>3rd Indent             | Long-term use                                                                                                                                                     |

| <b>Product description</b>                                                           | <b>Class</b> | <b>Rule</b>             | <b>Comments</b>                                                                              |
|--------------------------------------------------------------------------------------|--------------|-------------------------|----------------------------------------------------------------------------------------------|
| Brackets                                                                             | IIa          | Rule 5                  | Long-term use                                                                                |
| Calcium hydroxide,<br>Calcium salicylate,<br>Calcium sulfate                         | IIa          | Rule 8                  |                                                                                              |
| Expansion screws                                                                     | IIa          | Rule 5, 3rd Indent      | Long-term use                                                                                |
| Dental implants and abutments                                                        | IIb          | Rule 8                  | Long-term use, not placed “in the teeth”, therefore not Class IIa                            |
| Dental implants, biological coated                                                   | III          | Rule 8<br>3rd Indent    | If biological action is claimed                                                              |
| Desensitizer                                                                         | I            | Rule 5<br>1st Indent    | For transient use                                                                            |
|                                                                                      | I            | Rule 5<br>second Indent | For short-term use in the oral cavity                                                        |
| Excavator, dental                                                                    | Ir           | Rule 6                  | Surgical invasive instrument, reprocessable                                                  |
| Pit and fissure sealant                                                              | IIa          | Rule 5 or<br>Rule 8     |                                                                                              |
| Filling materials (composite, glass-ionomer-cements, ceramic inlays, galvano inlays) | IIa<br>IIa   | Rule 8<br>Rule 19       | If nanomaterial is present<br>Potential for internal exposure of nanomaterials is negligible |
| Filling materials (temporary, provisional)                                           | IIa          | Rule 7 or 8             | Depending on usage time                                                                      |
| Attachments                                                                          | IIa          | Rule 8                  | Fixed, long-term use                                                                         |
| Holding elements, orthodontic                                                        | IIa          | Rule 5                  | Invasive product, used in the oral cavity                                                    |
| Handpieces and angled pieces (connected on motor)                                    | IIa          | Rule 9                  |                                                                                              |
| Bone Rongeur, gouge pliers                                                           | Ir           | Rule 5                  |                                                                                              |
| Interdental wedge                                                                    | I            | Rule 5                  |                                                                                              |
| Handpiece with cold light                                                            | I            | Rule 13                 | Ir product, if reprocessing is required                                                      |
| Cannulas, sterile or non-sterile                                                     | I            | Rule 5                  | As addition on syringes                                                                      |
| Cavity varnish                                                                       | IIa          | Rule 8                  |                                                                                              |
| Cavity cleaning agents                                                               | IIa          | Rule 6                  |                                                                                              |
| Clamping wire                                                                        | IIa          | Rule 5,<br>3rd Indent   | for long-term use<br>(see also braces)                                                       |

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| <b>Product description</b>                                             | <b>Class</b> | <b>Rule</b>                     | <b>Comments</b>                                                                                                                |
|------------------------------------------------------------------------|--------------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Bonder                                                                 | Ila          | Rule 8                          | Because the tooth is conditioned by insertion, the requirement “in the teeth” is fulfilled<br>(see also adhesives and cements) |
| Clamp, artery<br>Haemostatic Forceps                                   | Ir           | Rule 6                          |                                                                                                                                |
| Rubber Dam, Rubber Dam<br>Frame<br>Support structure for rubber<br>dam | I            | Rule 5                          |                                                                                                                                |
| Conditioner                                                            | Ila          | Rule 6                          | Transient use                                                                                                                  |
| Bone replacement materials                                             | Ila<br>III   | Rule 8<br>Rule 8                | Not resorbable<br>Resorbable                                                                                                   |
| Crowns, dental crowns                                                  | Ila          | Rule 8                          |                                                                                                                                |
| Crown and bridge materials<br>(temporary, provisional)                 | Ila          | Rule 7 or 8<br>Rule 19          | Depending on usage time<br>If nanomaterial is present                                                                          |
| Artificial teeth                                                       | I            | Rule 5                          |                                                                                                                                |
| Varnishers (protective<br>varnishers, fluoriding<br>varnishers)        | I            | Rule 5,<br>1st or 2nd<br>Indent | Short-term or transient use                                                                                                    |
| Alloys (for crowns, bridges,<br>inlays, prosthetics)                   | Ila          | Rule 8                          | Placed “in the teeth”                                                                                                          |
| Polymerizing devices for<br>hardening                                  | I<br>Ila     | Rule 13<br>Rule 9               | Stand alone<br>If connection for MD of class Ila is<br>present                                                                 |
| Liner                                                                  | Ila          | Rule 8<br>or Rule 19            | If nanomaterial is present                                                                                                     |
| Colours for staining                                                   | Ila<br>I     | Rule 8<br>Rule 5                | For removable prostheses                                                                                                       |
| Materials for guided tissue<br>regeneration                            | IIb<br>IIb   | Rule 8<br>Rule 9                | Not resorbable<br>Resorbable                                                                                                   |
| Materials against bruxism                                              | I            | Rule 5                          |                                                                                                                                |
| Multifunctional handpieces                                             | Ila          | Rule 9                          | Intended for connection to medical<br>device, Class Ila                                                                        |
| Chisel, Bone                                                           | Ir           | Rule 6                          | Surgically-invasive                                                                                                            |
| Knife holder                                                           | Ir           | Rule 6                          | Surgically-invasive                                                                                                            |
| Microsurgical instruments<br>(scissors, needle holder,<br>forceps)     | Ir           | Rule 6                          | “Ir” in cases the instruments are being<br>used surgically-invasive                                                            |

| <b>Product description</b>                                                                           | <b>Class</b> | <b>Rule</b>                 | <b>Comments</b>                                                                                                                                                                                                                                                    |
|------------------------------------------------------------------------------------------------------|--------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Mixing cannula                                                                                       | I            | Rule 5                      | invasive use                                                                                                                                                                                                                                                       |
|                                                                                                      | IIa          | Rule 6                      | Surgically invasive use                                                                                                                                                                                                                                            |
| Dental casting alloys                                                                                | IIa          | Rule 5                      | Long-term use in oral cavity                                                                                                                                                                                                                                       |
| Motor, air driven, turbines                                                                          | IIa          | Rule 9                      |                                                                                                                                                                                                                                                                    |
| Mouth Gag, Mouth Gag Retractor                                                                       | I            | Rule 5                      |                                                                                                                                                                                                                                                                    |
| Suture materials                                                                                     | IIa          | Rule 7                      | Not resorbable                                                                                                                                                                                                                                                     |
|                                                                                                      | III          | Rule 7, 14 or 18            | Resorbable, with drugs                                                                                                                                                                                                                                             |
| Paper points for root-canal cleaning and drying                                                      | IIa          | Rule 5                      |                                                                                                                                                                                                                                                                    |
| Parapulpal pins                                                                                      | IIa          | Rule 8                      |                                                                                                                                                                                                                                                                    |
| Polishing pastes                                                                                     | I            | Rule 5,<br>1st Indent       | Short-term use in the oral cavity;<br>Product is used for surface smoothing. Application to polishing rollers for spreading on the area to be polished. Subsequent suction or rinsing, therefore no absorption from the body, therefore no application of rule 21. |
| Polishing strips, separating strips, interproximal strips                                            | I            | Rule 5,<br>2nd Indent       | No connection to an active device; no active devices;<br>Strips are no surgical instruments, therefore not class 1r, unless placed in the market sterile                                                                                                           |
| Prophylaxis powder, blasting powder, dental<br>Used together with powder jet instruments (see below) | I            | Rule 5<br>1st or 2nd Indent | Transient use<br>or in case of application in the oral cavity,<br>also in the case of subgingival application class 1 and rule 5, because there is no surgically invasive use                                                                                      |
|                                                                                                      | IIa          | Rule 19                     | If nanomaterial is present                                                                                                                                                                                                                                         |
| Prosthodontic materials                                                                              | IIa          | Rule 5                      |                                                                                                                                                                                                                                                                    |
| Denture adhesive (cream, powder)                                                                     | IIa          | Rule 21,<br>3rd Indent      | Application in the oral cavity                                                                                                                                                                                                                                     |
| Relining materials for prostheses                                                                    | IIa          | Rule 21,<br>3rd Indent      | Application in the oral cavity                                                                                                                                                                                                                                     |
| Pulp capping material                                                                                | IIa          | Rule 8                      | Without drug substance                                                                                                                                                                                                                                             |
|                                                                                                      | III          | Rule 14                     | With drug substance                                                                                                                                                                                                                                                |
| Pulp vitality measuring device                                                                       | IIa          | Rule 10                     |                                                                                                                                                                                                                                                                    |

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| <b>Product description</b>                                                              | <b>Class</b> | <b>Rule</b>                 | <b>Comments</b>                                                                                                                                                                                    |
|-----------------------------------------------------------------------------------------|--------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Powder jet handpieces                                                                   | IIa          | Rule 9                      | Air-driven Handpieces, used for therapeutic purposes through radiated cleaning powder                                                                                                              |
| Retention pins/root posts                                                               | IIa          | Rule 8                      |                                                                                                                                                                                                    |
| Retraction cords, - rings                                                               | I<br>III     | Rule 5<br>Rule 14           | Without drug substance<br>With drug substance                                                                                                                                                      |
| Retraction paste                                                                        | IIa          | Rule 4<br>Rule 19           | Due to haemostatic effect<br>If nanomaterial is present                                                                                                                                            |
| Direction gauge/<br>Parallelization pin/<br>Positioning guide                           | I            | Rule 5                      |                                                                                                                                                                                                    |
| X-ray film                                                                              | IIa          | Rule 17                     |                                                                                                                                                                                                    |
| X-ray sensor, dental                                                                    | IIa          | Rule 17                     |                                                                                                                                                                                                    |
| X-ray imaging plate, dental                                                             | IIa          | Rule 17                     |                                                                                                                                                                                                    |
| Dental Scaler (electrically or air-driven)                                              | IIa          | Rule 9                      | Dental Scaler handpieces, used electrically or air-driven, in combination with scaler tips for dental treatment                                                                                    |
| Protected varnish (see varnishes)                                                       | I            | Rule 5                      |                                                                                                                                                                                                    |
| Silanisation materials                                                                  | IIa          | Rule 8                      |                                                                                                                                                                                                    |
| Sprays                                                                                  | I            | Rule 5                      | If nanomaterial is present: Potential for internal exposure of nanomaterials is negligible<br><br>Application in the oral cavity<br>Potential for internal exposure of nanomaterials is negligible |
| Anti fog sprays for intraoral mirrors                                                   | I            | Rule 5                      |                                                                                                                                                                                                    |
| Occlusion sprays                                                                        | IIa          | Rule 19                     |                                                                                                                                                                                                    |
| Intraoral scan sprays                                                                   | IIa          | Rule 21                     |                                                                                                                                                                                                    |
| Power sprays                                                                            | IIa          | Rule 19                     |                                                                                                                                                                                                    |
| Syringes single-use, sterile                                                            | IIa          | Rule 6                      |                                                                                                                                                                                                    |
| Pivot teeth                                                                             | IIa          | Rule 8                      |                                                                                                                                                                                                    |
| Blasting abrasives/Powder for dental cleaning including scaling, see prophylaxis powder | I            | Rule 5<br>1st or 2nd Indent |                                                                                                                                                                                                    |
| Tamponades                                                                              | I<br>III     | Rule 5<br>Rule 14           | Without drug substance<br>With drug substance                                                                                                                                                      |
| Turbines, dental                                                                        | IIa          | Rule 9                      | High-speed turbine handpiece, air-driven                                                                                                                                                           |

| <b>Product description</b>                                       | <b>Class</b> | <b>Rule</b>          | <b>Comments</b>                                                                                                                                                                                                                      |
|------------------------------------------------------------------|--------------|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Lining materials (cavity)                                        | IIa          | Rule 8               | Placed “in the teeth”                                                                                                                                                                                                                |
| Lining materials (cavity)                                        | IIa          | Rule 19              | If nanomaterial is present, Potential for internal exposure of nanomaterials is negligible                                                                                                                                           |
| Veneer,<br>Veneering materials                                   | IIa<br>IIb   | Rule 8<br>Rule 8     | If placed “in the teeth”                                                                                                                                                                                                             |
| All-ceramics                                                     | IIa          | Rule 8               |                                                                                                                                                                                                                                      |
| Waxes, intraoral                                                 | I            | Rule 5               |                                                                                                                                                                                                                                      |
| Cotton rolls                                                     | I            | Rule 5               |                                                                                                                                                                                                                                      |
| Retractor                                                        | Ir           | Rule 6               | surgically-invasive                                                                                                                                                                                                                  |
| Wound dressing in the oral cavity                                | I            | Rule 5               |                                                                                                                                                                                                                                      |
| Endodontic filling materials                                     | IIa<br>III   | Rule 8<br>Rule 14    | Without drug substance<br>With drug substance                                                                                                                                                                                        |
| Endodontic rinsing solutions                                     | IIa          | Rule 6               | Transient use, surgically-invasive product.<br>If the rinsing solution contains chelators (EDTA or citric acid), it is a medical device. In case of NaOCL 5 % it is in Germany pharmaceutical, in other EU-countries medical device. |
| Endodontic points                                                | IIa          | Rule 8               | analogue retention pins, see above                                                                                                                                                                                                   |
| Tooth crowns                                                     | IIa          | Rule 8               |                                                                                                                                                                                                                                      |
| Periodontal probe                                                | I            | Rule 5               |                                                                                                                                                                                                                                      |
| Tooth forming devices<br>(consisting of bonder, brackets, wires) | IIa          | Rule 5<br>3rd Indent | Long-term use                                                                                                                                                                                                                        |
| Scaler, ultrasound                                               | IIa          | Rule 12              |                                                                                                                                                                                                                                      |
| Forceps (extraction -, tissue-, root splinter forceps)           | Ir           | Rule 6               | surgically invasive use;<br>forceps, which come into contact with open wounds                                                                                                                                                        |
| Cements                                                          | IIa          | Rule 8<br>Rule 19    | (See also adhesives and bonder)<br>If nanomaterial is present,<br>Potential for internal exposure of nanomaterials is negligible                                                                                                     |

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| <b>Product description</b>                                      | <b>Class</b> | <b>Rule</b>                       | <b>Comments</b>                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------|--------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Impression material                                             | IIa<br><br>I | Rule 19, 3rd Indent<br><br>Rule 5 | If nanomaterial is present:<br>Potential for internal exposure of nanomaterials is negligible.<br><br>In contact with damaged mucosa.<br><br>Without nanomaterial respectively without potential of internal exposure.                                |
| Impression post                                                 | I<br><br>Ir  | Rule 5<br><br>Rule 6              | For transient use; No multiple use and no reprocessing; No contact with open wounds<br><br>Surgically invasive use in cases, the product is used immediately after insertion of implants and might come into contact with blood and/or damaged mucosa |
| Impression (not reprocessable)                                  | I            | Rule 5                            |                                                                                                                                                                                                                                                       |
| Adhesives for impression materials                              | I            | Rule 5                            |                                                                                                                                                                                                                                                       |
| Adhesives                                                       | IIa          | Rule 8                            | Placed “in the teeth”                                                                                                                                                                                                                                 |
| Etching products (intraoral)                                    | IIa<br>IIa   | Rule 6<br>Rule 19                 | Transient use<br>If nanomaterial is present                                                                                                                                                                                                           |
| Electrocautery                                                  | IIb          | Rule 9                            |                                                                                                                                                                                                                                                       |
| Face bows                                                       | I<br>IIa     | Rule 5<br>Rule 5<br>3rd Indent    | For long-term use                                                                                                                                                                                                                                     |
| Polymer materials for dental trays                              | I<br>IIa     | Rule 5<br>Rule 5                  | Transient or short-term use<br>Long-term use                                                                                                                                                                                                          |
| Thermoforming materials for aligners and retainers, orthodontic | I            | Rule 5                            | Short-term use                                                                                                                                                                                                                                        |
| Coiled springs, orthodontic                                     | IIa          | Rule 5                            | Long-term use                                                                                                                                                                                                                                         |
| Elastomeric auxiliaries, orthodontic                            | IIa          | Rule 5                            | Long-term use                                                                                                                                                                                                                                         |
| Bands, orthodontic                                              | IIa          | Rule 5                            | Long-term use                                                                                                                                                                                                                                         |

## 6 Non-invasive devices

### 6.1 Basic overview

**Table 3 — Non-invasive devices**

| Intended use                                        | Rule | Suggested Class |
|-----------------------------------------------------|------|-----------------|
| Denture cleansers with a disinfecting function      | 15   | II A            |
| Orthodontic materials and devices, extra oral parts | 1    | I               |

### 6.2 Examples for non-invasive devices

| Product Description                                                           | Class        | Rule                  | Comments                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------|--------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Applications-dispenser                                                        | I            | Rule 5                |                                                                                                                                                                                                                                                                       |
| Disinfections                                                                 | IIa<br>IIb   | Rule 16<br>Rule 16    | Disinfection solutions used for disinfection of invasive products as end point of processing                                                                                                                                                                          |
| Photographic chemicals for X-ray film development                             | I            | Rule 1                |                                                                                                                                                                                                                                                                       |
| Instrument stand (bur holder)                                                 | I            | Rule 1                | Accessory for transport of (re-) processable and storage of rotary instruments                                                                                                                                                                                        |
| Cannulas for extraoral suction                                                | I            | Rule 1                |                                                                                                                                                                                                                                                                       |
| Dental Compressor, dental air                                                 | IIa<br><br>I | Rule 9<br><br>Rule 13 | Intended purpose supply dental air directly to the instruments (dental hand pieces like: syringe, air turbine etc.): Rule 9 risk class IIa.<br><br>Intended purpose supply dental air through the main line for dental air to the dental units: Rule 13 risk class I. |
| Gauges for verification measurements, Calipper                                | I            | Rule 5                |                                                                                                                                                                                                                                                                       |
| X-ray film developer, dental                                                  | I            | Rule 1                |                                                                                                                                                                                                                                                                       |
| X-ray equipment, dental                                                       | IIb          | Rule 10               |                                                                                                                                                                                                                                                                       |
| Other devices and materials for the preparation of custom-made dental devices | I            | Class 1               | Devices according EMDN-Nomenclature under Q010699 (materials for the preparation of custom-made dental devices – other)                                                                                                                                               |
| Sterile material container                                                    | I            | Rule 1                |                                                                                                                                                                                                                                                                       |
| Sterilizer                                                                    | I            | Rule 13               |                                                                                                                                                                                                                                                                       |



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| Product Description     | Class | Rule   | Comments |
|-------------------------|-------|--------|----------|
| Face masks, orthodontic | I     | Rule 1 |          |
| Headgear, orthodontic   | I     | Rule 1 |          |

**7 Instruments****7.1 Basic overview****Table 4 — Instruments**

| Intended use                                                     | Rule | Class             |
|------------------------------------------------------------------|------|-------------------|
| <b>Power operated instruments</b>                                |      |                   |
| Diagnostic probe with a measuring function                       |      |                   |
| invasive and energy driven                                       | 10   | II A              |
| surgically invasive and energy driven                            | 6    | II A              |
| Dental handpieces for rotary instruments                         | 9    | II A              |
| Rotary instruments for connection to dental handpieces           |      |                   |
| surgically invasive                                              | 6    | II A              |
| invasive (polishing and prophylactic devices)                    | 5    | II A              |
| non invasive                                                     | 1    | I                 |
| Powered devices for surgical treatment, non-rotary               | 9    | IIA               |
| Energy driven injection devices                                  | 6    | IIA               |
| <b>Hand operated instruments</b>                                 |      |                   |
| Diagnostic probe with a measuring function,<br>not energy driven | 5    | I (M)             |
| NOTE (M) means approval of the measuring system.                 |      |                   |
| Reusable hand instruments                                        |      |                   |
| invasive                                                         | 5    | I                 |
| surgically invasive                                              | 6    | I (r)             |
| Single use hand instruments                                      |      |                   |
| invasive                                                         | 5    | I (transient use) |
| surgically invasive                                              | 6    | IIa               |

**7.2 Examples for instruments**

| <b>Product designation</b>                                                                                                                        | <b>Class</b> | <b>Rule</b>                          | <b>Comments</b>                                                                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Impression form, dental                                                                                                                           | I            | Rule 5                               |                                                                                                                                                                                  |
| Impression tray                                                                                                                                   | I            | Rule 5<br>first Indent               | transient use;<br>no surgical-invasive<br>instrument, therefore no Class<br>Ir product                                                                                           |
| Syringe with anaesthetic<br>(cartridge syringe) without<br>injection needle                                                                       | I            | Rule 5                               |                                                                                                                                                                                  |
| Applications syringes/cannulas                                                                                                                    | I            | Rule 5                               | invasive (e.g. for impression<br>materials)                                                                                                                                      |
|                                                                                                                                                   | IIa          | Rule 6                               | surgical-invasive (e.g. for<br>cements)                                                                                                                                          |
| Amalgam carrier                                                                                                                                   | I            | Rule 5                               |                                                                                                                                                                                  |
| Bur sleeves, stop sleeves                                                                                                                         | I            | Rule 5,<br>first part of<br>sentence | Products are used for<br>transient use of X-ray<br>verification of prosthetic<br>requirements and for guiding<br>surgical instruments. Invasive<br>use in natural body openings. |
| Dental syringe (impression<br>material, rinsing)                                                                                                  | I            | Rule 5                               |                                                                                                                                                                                  |
| Insertion tools, manual<br>Screw driver for bone<br>screws/pins<br>Membrane holder<br>Needle holder                                               | I<br>Ir      | Rule 5<br>Rule 6,<br>second Indent   | Use with surgical-invasive<br>indication                                                                                                                                         |
| Elevator, dental                                                                                                                                  | Ir           | Rule 6                               | surgical invasive instrument,<br>reprocessable                                                                                                                                   |
| Excavator, dental                                                                                                                                 | Ir           | Rule 6                               | surgical invasive instrument,<br>reprocessable                                                                                                                                   |
| Mallet, dental                                                                                                                                    | I            | Rule 5                               |                                                                                                                                                                                  |
| Hand instruments, surgical, e.g.<br>spoons, root elevators,<br>periosteal, gingiva stance,<br>bone scraper, luxation<br>instruments, syndesmeotom | Ir           | Rule 6                               |                                                                                                                                                                                  |
| Hand instruments, endodontic<br>(endodontic, endodontic<br>ruler/, endodontic spreaders,<br>guttapercha remover)                                  | Ir           | Rule 6                               |                                                                                                                                                                                  |

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| <b>Product designation</b>                                                                        | <b>Class</b> | <b>Rule</b>             | <b>Comments</b>                                                                |
|---------------------------------------------------------------------------------------------------|--------------|-------------------------|--------------------------------------------------------------------------------|
| hand instruments, periodontal<br>e.g. tunneling instruments,<br>periodontal gingivectomy<br>knife | Ir           | Rule 6                  |                                                                                |
| rongeurs                                                                                          | Ir           | Rule 5                  |                                                                                |
| Interdental wedges                                                                                | I            | Rule 5                  |                                                                                |
| Cannulas for intraoral suction                                                                    | Ila          | Rule 5                  | Connection to an active<br>device;<br>Invasive suction on tooth                |
|                                                                                                   | Ila          | Rule 6                  | Surgical invasive suction on<br>jaw bone                                       |
| Cannulas, sterile or non-sterile                                                                  | I            | Rule 5                  | As addition on syringes                                                        |
| Crinch, arteriell                                                                                 | Ir           | Rule 6                  |                                                                                |
| Bone file                                                                                         | Ir           | Rule 6                  |                                                                                |
| Bone mill                                                                                         | Ila          | Rule 2                  | For lead through and storage<br>of tissues for use or insertion<br>in the body |
| Bone scraper (without blade)                                                                      | I            | Rule 5                  | Invasive, transient use<br>surgical invasive use                               |
| Bone scraper (with blade)                                                                         | Ir           | Rule 6<br>second Indent |                                                                                |
| Dental dam<br>Support structure for dental<br>dam                                                 | I            | Rule 5                  |                                                                                |
| Crown/inlay remover                                                                               | I            | Rule 5                  |                                                                                |
| Curette                                                                                           | Ir           | Rule 6                  | surgical-invasive                                                              |
| Spoons for gels                                                                                   | I            | Rule 5                  |                                                                                |
| Matrices/- holder                                                                                 | I            | Rule 5                  |                                                                                |
| Chisel bone                                                                                       | Ir           | Rule 6                  | surgical-invasive                                                              |
| Knife holder                                                                                      | Ir           | Rule 6                  | surgical-invasive                                                              |
| Rules for proofing<br>measurements                                                                | I            | Rule 5                  |                                                                                |
| Microsurgical instruments<br>(scissors, needle holder,<br>tweezers)                               | Ir           | Rule 6                  | surgical-invasive                                                              |
| Mouth blocker                                                                                     | I            | Rule 5                  |                                                                                |
| Intraoral mirrors                                                                                 | I            | Rule 5                  |                                                                                |
| Osteotome                                                                                         | Ir           | Rule 6                  | surgical-invasive                                                              |
| Periodontometer                                                                                   | I            | Rule 5                  | Used in gum openings, but not<br>“surgical-invasive”.                          |

| <b>Product designation</b>                                                    | <b>Class</b> | <b>Rule</b>             | <b>Comments</b>                                                                |
|-------------------------------------------------------------------------------|--------------|-------------------------|--------------------------------------------------------------------------------|
| Polisher, polishing discs<br>(connected to a handpiece)                       | Ila          | Rule 5<br>last Sentence | Connection to an active device<br>of Class Ila                                 |
| Ratchet wrench<br>Torque wrench<br>Ratchet wrench insert                      | I            | Rule 5                  | non surgical invasive                                                          |
| Ratchet wrench<br>Torque wrench<br>Ratchet wrench insert                      | Ir           | Rule 6                  | surgical invasive                                                              |
| Rotary instruments,<br>connected to an active<br>handpiece, surgical invasive | Ila          | Rule 6                  |                                                                                |
| Rotary instruments, connected<br>to a handpiece, invasive                     | Ila          | Rule 5                  |                                                                                |
| Spatula                                                                       | I            | Rule 5                  |                                                                                |
| Syringes, reusable                                                            | I            | Rule 5                  |                                                                                |
| Syringes once, sterile                                                        | Ila          | Rule 6                  |                                                                                |
| Hooks                                                                         | Ir           | Rule 6                  | surgical-invasive                                                              |
| Endodontic instruments                                                        | Ir<br>Ila    | Rule 6<br>Rule 6        | surgical invasive instrument                                                   |
| Explorer                                                                      | I            | Rule 5                  |                                                                                |
| Forceps, dental                                                               | I            | Rule 5                  |                                                                                |
| Forceps (extraction -, tissue-,<br>root- forceps)                             | Ir           | Rule 6                  | surgical invasive use;<br>forceps, which come into<br>contact with open wounds |
| Suction equipment - cannula                                                   | Ila          | Rule 5                  | Rule 5 last sentence:<br>connection to an active device                        |
| Syringe with anaesthetic<br>(cartridge syringe) without<br>injection needle   | I            | Rule 5                  |                                                                                |
| Cannulas, sterile or non-sterile                                              | I            | Rule 5                  | As addition on syringes                                                        |
| Clamp, artery<br>Haemostatic Forceps                                          | Ir           | Rule 6                  |                                                                                |
| Orthodontic instruments                                                       | I            | Rule 5                  | Band removing pliers,<br>orthodontic palatal expansion<br>screwdrivers         |

**CEN/TR 12401:2025 (E)****8 Equipment****8.1 Basic overview****Table 5 — Equipment**

| <b>Intended use</b>                                                    | <b>Rule</b> | <b>Class</b> |
|------------------------------------------------------------------------|-------------|--------------|
| Multifunctional air and water syringes connected to a dental unit      | 12          | II A         |
| Single use tips                                                        |             |              |
| for multifunctional syringes                                           | 5           | II A         |
| for suction equipment                                                  | 5           | II A         |
| Dental unit incorporating, controlling or monitoring                   |             |              |
| active devices in class II B                                           | 9           | II B         |
| active devices in class II A                                           | 9           | II A         |
| Amalgam separator used as an integral part of the dental unit          |             |              |
| Type 2, Type 3                                                         | 1           | I            |
| Type 1, Type 4                                                         | 13          | I            |
| Dental operating light                                                 | 13          | I            |
| Devices for cleaning and disinfection of:                              |             |              |
| Non invasive devices                                                   | 16          | II A         |
| Invasive devices                                                       | 16          | IIB          |
| Cautery                                                                | 9           | II B         |
| High frequency electrosurgery unit                                     | 9           | II B         |
| Diagnostic fibreoptic handpieces                                       | 12          | I            |
| Laser unit, dental                                                     |             |              |
| non surgical                                                           | 9           | II A         |
| surgical                                                               | 9           | II B         |
| Low voltage motor drive for handpieces                                 | 9           | II A         |
| Air motor drive for handpieces                                         | 9           | II A         |
| Dental patient chair                                                   | 1           | I            |
| Dental curing light with handpieces                                    | 9           | II A         |
| Pulp tester                                                            | 10          | II A         |
| Dental radiographic equipment                                          | 10          | II B         |
| Ultrasonic scaler including handpiece                                  | 9           | II A         |
| Dental radiographic imaging systems with a part applied to the patient | 16          | II A         |
| NOTE Stand alone software is considered to be an active device.        |             |              |

| Intended use                                                                     | Rule | Class |
|----------------------------------------------------------------------------------|------|-------|
| Chair side CAD-CAM systems with or without intra oral registration               | 1    | I     |
| Lubricants for invasive devices (such as dental handpieces)                      | 1    | I     |
| Powered mixing devices used in the dental surgery, accessory to dental materials | 1    | I     |

## 8.2 Example for equipment

| Product description                                | Class    | Rule                | Comments                                                                 |
|----------------------------------------------------|----------|---------------------|--------------------------------------------------------------------------|
| Data management systems for dental X-ray images    | IIb      | Rule 11, 2nd indent |                                                                          |
| Dental treatment unit                              | IIa      | Rule 9              |                                                                          |
| Dental operating light                             | I        | Rule 13             |                                                                          |
| Diagnostic devices, dental                         | IIa      | Rule 10             | Devices for supporting dental diagnosis                                  |
| Digital registration unit                          | I        | Rule 13             |                                                                          |
| Electrocautery                                     | IIb      | Rule 9              |                                                                          |
| High frequency devices, surgical                   | IIb      | Rule 9              |                                                                          |
| Imaging plate scanner                              | I        | Rule 1 and Rule 13  |                                                                          |
| Intraoral camera                                   | I        | Rule 13             | Active medical device                                                    |
| Laser devices (for connection to laser handpieces) | IIb      | Rule 9              |                                                                          |
| Mixing devices                                     | I<br>I   | Rule 1<br>Rule 13   | If manual use<br>If active medical device                                |
| Patient chair, dental                              | I        | Rule 13             | Active product, not suitable for administer                              |
| Polymerisation lamps                               | IIa      | Rule 9              | If intended to a medical device class IIa                                |
| Polymerizing devices for hardening                 | I<br>IIa | Rule 13<br>Rule 9   | Stand alone<br>If connection for medical devices of class IIa is present |
| Powder devices for dental treatment                | IIa      | Rule 12             |                                                                          |
| Pressure air cleaner, drying of teeth              | IIa      | Rule 12             |                                                                          |

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| <b>Product description</b>            | <b>Class</b> | <b>Rule</b>        | <b>Comments</b>                                                                                                                                                                                                |
|---------------------------------------|--------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suction equipment                     | IIa<br>I     | Rule 12<br>Rule 13 | Active MD for removal of body liquids from the body. "Suction equipment", directly connected to the cannula connectors, covered by Rule 12 class IIa. "Central suction source equipment", Rule 13 and class I. |
| Ultrasonic device for dental cleaning | IIa          | Rule 9             |                                                                                                                                                                                                                |
| X-ray devices, dental                 | IIb          | Rule 10            |                                                                                                                                                                                                                |
| X-ray film developer                  | I            | Rule 1             |                                                                                                                                                                                                                |
| X-ray equipment                       | IIb          | Rule 10            |                                                                                                                                                                                                                |
| X-ray image viewer, dental            | I            | Rule 13            |                                                                                                                                                                                                                |
| X-ray imaging plate, dental           | IIa          | Rule 17            |                                                                                                                                                                                                                |
| Disinfection devices                  | IIa<br>IIb   | Rule 16<br>Rule 16 | Cleaning-/disinfection devices used for disinfection of invasive products as end point of processing                                                                                                           |
| Polymerizing devices for hardening    | I<br>IIa     | Rule 13<br>Rule 9  | Stand alone<br>If connection for MD of class IIa is present                                                                                                                                                    |

## **Bibliography**

- [1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- [2] MDCG 2021-24 Guidance on classification of medical devices” as prepared by the Medical Device Coordination Group (MDCG)
- [3] MDCG 2022-05 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices