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Dentistry - Guidance on the classification of dental devices and accessories

Zahnheilkunde - Anleitung zur Klassifizierung von Dentalprodukten und Zubehör

Art dentaire - Guide de classification des dispositifs dentaires et accessoires

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This Technical Report was approved by CEN on 12 January 2003. It has been drawn up by the Technical Committee CEN/TC 055.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (CEN/TR 12401:2003) has been prepared by Technical Committee CEN/TC 55 “Dentistry”, the secretariat of which is held by DIN.

This document supersedes CEN/CR 12401:1996.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

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 Council Directive 93/42 EEC of 14 June 1993 concerning medical devices. The Directive 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 Directive.

The classification should be acceptable to Notified Bodies (NB) and Competent Authorities (CA). The Directive describes procedures for resolving any disputes over classification between manufacturers, Notified Bodies and Competent Authorities.

The European Commission has developed a document "Guidelines for the Classification of Medical Devices". This CEN Technical Report is intended to complement that guidance. In addition, NB-MED, European Co-ordination of Notified Bodies, have developed a series of consensus statements which also have been taken into consideration. It will, therefore, be of value to manufacturers in making decisions with regard to the likely classification of particular devices.

1 Scope

This CEN Technical Report provides guidance on the application of the classification rules in Council Directive 93/42 EEC of 14 June 1993 concerning medical devices as they pertain to dental devices and accessories.

2 Classification of dental devices and accessories

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

Materials and other prefabricated devices that will be part of a custom made device are included in this guidance document. Custom made devices are not. Some materials can be used both for long term and short term custom made devices. The intended purpose claimed by the manufacturer will then be decisive for the classification. In this document the implementing rule 2.5 of the Directive has been used for the proposed classification, i.e. ”the strictest rules.....shall apply”.

It is recommended that this list be considered in conjunction with the Directive 93/42 EEC [1] and the ”Guidelines to the classification of medical devices” (MEDDEV 2.4/1, latest revision) [2], as prepared by the Commission (see Bibliography).

3 Proposals for classification of dental devices

Proposals for classification are given in Tables 1 to 5.

Table 1 — Invasive devices used in the oral cavity

Intended use	Rule	Suggested Class
Long term use (more than 30 days)		
Plastic materials for direct insertion metals polymers cements	8	II A
Cavity lining materials	8	II A
Dentine adhesives	8	II A
Pit and fissure sealants	5	II A
Protective film (long term)	5	II A
Pulp capping materials non medicated medicated	 8 13	 II A III
Endodontic filling materials sealers points retrograde root canal filling materials	8	II A

Intended use	Rule	Suggested Class
Luting materials water based cements eugenol based cements polymer based cements	8	II A
Materials for fixed protheses and inlays metals ceramics and glass polymers	8	II A
Materials for removable prostheses including maxillofacial prostheses metals ceramics polymers NOTE Materials for removable protheses used explicitly for protheses to be removed by the patient can be in Class I	5	II A
Endostabilizers/Transendodontic implants	8	II B
Precision retainers/Attachments	8	II A
Orthodontic materials and devices, intraoral use metals ceramics polymers	5	II A
Dental implants metals ceramics and glass polymers carbon based calcium based	8	II B
Dental implants, biologically active coating	8	III
Bone substitutes non resorbable resorbable	 8 8	 II B III
Materials for guided tissue regeneration non resorbable resorbable	 8 8	 II B III
Osteo-synthesis devices	8	III
Short term use (max. 30 days)		
Protective films (varnish)	5	I
Protective films, medicated NOTE Films with a primary function of slow release of medicines are a medicinal product	13	III
Temporary filling materials	7	II A

Intended use	Rule	Suggested Class
Temporary crowns and bridges prefabricated materials for custom made temporary devices	7	II A
Short term relining and tissue conditioning materials non medicated medicated	 5 13	 I III
Surgical packs (dressings) Surgical packs, medicated	7 13	II A III
Suture material, non absorbable Suture material, absorbable/medicated	7 13	II A III
Materials for protective mouth guards (other than materials for removable prostheses) NOTE Mouth guards for protection against injury from sport are covered by the "Personal Protective Directive".	5	I
Transient use (less than 60 min)		
Syringe tips for delivery of dental materials	5	I
Materials for surface preparation (etch, prime)	6	II A
Bleaching agents for intra dental bleaching professional use only	6	II A
Impression materials	5	I
Rubber dam	5	I
Cotton rolls, gaze, etc.	5	I
Wedges	5	I
Waxes	5	I
Retraction cords Retraction cords, medicated NOTE Astringents and haemostatic solutions are medicinal products	5 13	I III
Matrix bands	5	I
Impression trays	5	I
Endodontic absorbant points	6	II A
Polishing paste Polishing paste, medicated	5 13	I III
Polishing strips	5	I
Articulating, occlusion and bite registration devices	5	I
Radiographic devices	16	II A