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Dentistry — Guidance on the classification of dental devices and accessories

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National foreword

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Dentistry - Guidance on the classification of dental devices and accessories

Art dentaire - Lignes directrices pour la classification des dispositifs dentaires et accessoires

Zahnheilkunde - Anleitung zur Klassifizierung von Dentalprodukten und Zubehör

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Foreword

This document (CEN/TR 12401:2009) has been prepared by Technical Committee CEN/TC 55 “Dentistry”, the secretariat of which is held by DIN.

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This document supersedes CEN/TR 12401:2003.

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.

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, amended by Directive 2007/47/EC, 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 and accessories

Proposals for classification of dental devices and accessories 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

Table 1 *(continued)*

Endodontic filling materials sealers points retrograde root canal filling materials	8	II A
Luting materials water based cements eugenol based cements polymer based cements	8	II A
Materials for fixed prostheses and inlays metals ceramics and glass polymers	8	II A
Materials for removable prostheses and other intraorale appliances including maxillofacial prostheses metals ceramics polymers	5	II A
Endostabilizers / Transendodontic implants	8	II B
Prefabricated parts, surgically invasive, transient, short term or long term use (e.g. pins, posts, attachments)	6,7,8	II A
Orthodontic materials and devices, intraorale 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

Table 1 *(concluded)*

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
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
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 and accessories	5	I
Cotton rolls, gaze, etc.	5	I
Wedges	5	I
Waxes	5	I
Gingival retraction device Gingival retraction device, 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

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

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

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

Table 4 — Instruments

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

Table 5 — Equipment

Intended use	Rule	Suggested Class
Multifunctional air and water syringes connected to a dental unit	11	II A
Single use tips for multifunctional syringes for suction equipment	 5 5	 II A II A
High and medium volume suction equipment	11	II A
Dental unit incorporating, controlling or monitoring active devices in class II B active devices in class II A	 9 9	 II B II A
Amalgam separator used as an integral part of the dental unit	1	I
Dental operating light	12	I
Devices for cleaning and disinfection of : Non invasive devices Invasive devices	 15 15	 II A IIB
Cautery	9	II B
High frequency electrosurgery unit	9	II B
Diagnostic fiberoptic handpieces	12	I
Laser unit, dental non surgical surgical	 9 9	 II A 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 Note: Stand alone software is considered to be an active device	16	II A
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

Bibliography

Legal documents

[1] Council Directive 93/42 EEC of 14 June 1993 concerning medical devices, Official Journal of the European Union (OJEU) No. L. 169/1 of 1993-07-12, page 1 – 43; amended by Council Directive 2007/47/EC, OJEU No. L 247/21 of 2007-09-21

[2] MedDev 2.4.1, European Commission, Guidelines for the classification of Medical Devices (MedDev), Version 2.4.1, Rev. 8, July 2001

[3] Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC, Issue 05/00

Level 1 – Basic standards for medical devices

[4] EN ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[5] CEN ISO/TR 14969, *Medical devices — Quality management systems — Guidance on the application of ISO 13485*

[6] EN ISO 14971, *Medical devices — Application of risk management to medical devices*

Level 2 – Group standards for medical devices for dentistry

[7] EN 1639, *Dentistry — Medical devices for dentistry — Instruments*

[8] EN 1640, *Dentistry — Medical devices for dentistry — Equipment*

[9] EN 1641, *Dentistry — Medical devices for dentistry — Materials*

[10] EN 1642, *Dentistry — Medical devices used for dentistry — Dental implants*

[11] EN ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[12] EN 21942, (Parts 1 to 4), *Dental vocabulary*

[13] EN ISO 1942-5, *Dental vocabulary – Part 5: Terms associated with testing (ISO 1942-5:1989)*

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