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Guidance on the classification of dental devices and accessories

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This CEN REPORT has been prepared by Technical Committee CEN/TC 55 "Dentistry" and has been approved by CEN on 1996-03-15.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This CEN Report has been prepared by the CEN/TC 55 "Dentistry", 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. Others 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 must be acceptable to Notified Bodies and Competent Authorities. The Directive describes procedures for resolving any disputes over classification between manufacturers, Notified Bodies and Competent Authorities.

The Commission is developing a document "Guidelines to Classification of Medical Devices". This CEN Report is intended to complement that guidance. It will, therefore, be of value to manufacturers in making decisions with regard to the likely classification of particular devices.

1 Scope

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

2 A classification of dental devices and accessories

The list of dental devices and accessories given in Table 1 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. Cursom 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 and the "Guidelines to the classification of medical devices" (Meddev 10/93, latest revision), as prepared by the Commission (see Bibliography).

Table 1

Proposals for classification of dental devices

INTENDED USE	RULE	SUGGESTED CLASS
1. Invasive devices used in the oral cavity (clinical use)		
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 films (long term)	5	II A
Pulp capping materials Non medicated Medicated	8 13	II A III
Endodontic filling materials Sealers Points Retrograde root canal filling materials	8	II A
Luting materials Water based cements Eugenol based cements Polymer based cements	8	II A
Materials for fixed prostheses and inlays Metals Ceramics and glass Polymers	8	II A
Materials for removable prostheses including maxillofacial prostheses Metals Ceramics Polymers	5	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 Dental implants, biologically active coating	8 8	II B 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	II B
Short term use (max 30 days)		
Protective films (varnish) Protective films, medicated Note: Films with a primary function of slow release of medicines are a medicinal product	5 13	I 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
Materials for protective mouth guards (other than materials for removable protheses	5	1
Transient use (less than 60 min)		
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, gauze, etc.	5	I
Dental floss, medicated	13	III
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	16	II A
2. Invasive devices, oral cavity, patient use		
Long term use		
Denture adhesives, cushions and relining materials	5	II A
Short term use		
Tray for gels	5	I
Temporary filling	6	II A
Denture adhesives, cushions and relining materials	5	I
3. Non invasive devices		
Orthodontic materials and devices, extraoral parts	1	I
4. Instruments		
Power operated instruments		
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
Hand operated instruments		

Reusable	6	I
Single use	6	II A
5. Equipment		
High and medium volume suction equipment	11	II A
Dental unit incorporating, control or monitoring active devices in class II B	9	II B
Dental unit incorporating, control or monitoring active device in class II A	9	II A
Dental operating light	12	I
Devices for disinfection of medical devices for dentistry	15	II A
Cautery	9	II B
High frequency electrosurgery unit	9	II B
Diagnostic fiberoptic handpieces	12	I
Laser unit dental, non surgical	9	II A
Laser unit dental, surgical	9	II B
Multifunctional syringe	11	II A
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	12	I
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
Diagnostic devices with a measuring function	12	I

ANNEX A

Bibliography

1. Council Directive 93/42 EEC of June 14, 1993, concerning medical devices
   Guidelines to the Classification of Medical Devices MEDDEV 10/93-rev.4, 6/7/1995

2. Level 1 - Basic standards for medical devices

EN 540:1993	Clinical investigations of medical devices for human subjects
EN 556	Sterilization of medical devices - Sterility assurance level for medical devices labelled "STERILE" - Requirements
prEN 980	Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
prEN 1041	Terminology, symbols, and information provided with medical devices - Information supplied by the manufacturer with medical devices
EN 30993	Biological testing of medical and dental materials and devices. Parts 1 to 12
EN 46001:1993	Quality system - Medical devices - Particular requirements for the application of EN 29001
EN 46002:1993	Quality system - Medical devices - Particular requirements for the application of EN 29002
prEN 724	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the non-active medical device industry
EN 50103	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for active medical devices

3. Level 2 - Group standards for medical devices for dentistry.

prEN 1639	Dentistry - Medical devices for dentistry - Instruments