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Standard Recommendation
S.R. CEN/TR 12401:2009

Dentistry - Guidance on the classification of dental devices and accessories

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English Version

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

This Technical Report was approved by CEN on 5 April 2009. It has been drawn up by the Technical Committee CEN/TC 55.

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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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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.

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Introduction

Dental products are marketed for long term, short term and transient use in the mouth. A large number of items have been developed to assist in the treatment and prevention of oral diseases and the handling of dental materials. In contrast to pharmaceuticals (medicinal products), many dental materials are intended to perform as implanted devices in the oral cavity with a minimum of degradation and release of substances, i.e. their main action is to replace lost and defective teeth and oral tissue. Some materials contain elements that may initiate toxic or allergic responses. Other materials have additions of medicinal substances.

Many dental materials, instruments, equipment and disposables are covered by the 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.

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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

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