

SLOVENSKI STANDARD SIST CR 12401:2000

01-januar-2000

Guidance on the classification of dental devices and accessories

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Ta slovenski standard je istoveten z: CR 12401:1996

SIST CR 12401:2000

https://standards.iteh.ai/catalog/standards/sist/6283eef3-b1ac-424f-81b7-028ababce104/sist-cr-12401-2000

ICS:

11.060.01 Zobozdravstvo na splošno Dentistry in general

SIST CR 12401:2000 en

SIST CR 12401:2000

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REPORT RAPPORT BERICHT

CR 12401

May1996 mai 1996

Mai 1996

English version

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<u>SIST CR 12401-2000</u> https://standards.iteh.ai/eatalog/standards/sist/6283eef3-b1ac-424f-81b7-028ababce104/sist-cr-12401-2000

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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Page 2 CR 12401:1996

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 iTeh STANDARD PREVIE	W 8	II A
Dentine adhesives (standards.iteh.ai)	8	ΠA
Pit and fissure sealants	5	II A
Protective films (long term) ps://standards.iteh.ai/catalog/standards/sist/6283eef3-h1ac-42	4f.81h 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

Orthodortic			
Orthodontic materials and devices, intraoral use Metals	5	II A	
Ceramics			
Polymers			
Dental implants	8	II D	
Metals Commission and also		II B f (997) (168	
Ceramics and glass Polymers			
Carbon based	1	1. A. A. A. A.	
Calcium based			
Dental implants, biologically active coating	8	III	
Bone substitutes	8	II В	
Non resorbable Resorbable		пр	
	8	III	
Materials for guided tissue regeneration Non resorbable			
Resorbable	8	II B	
Osteo-synthesis devices	-	III	
Short term use (max 30 days)	8	ΠВ	
	ļ		
Protective films (varnish)	5 7 7 7 7 7 7 7 7 7 7	I i same	
Protective films, medicated iTeh STANDARD PREVIII Note:	13		
Films with a primary function of slow release of medicines are a			
medicinal product			
Temporary filling materials SIST CR 12401:2000 SIST CR 12401:2000 Littps://standards.iteh.ai/catalog/standards/sist/6283eef3-b1ac-42	4f-81h 7 -	ПА	
Temporary crowns and bridges 028ababce104/sist-cr-12401-2000			
Prefabricated	7	ПΑ	
Materials for custom made temporary devices			
Short term relining and tissue conditioning materials			
Non medicated Medicated	5	I	
	13	n	
Surgical packs (dressings) Surgical packs, medicated	7	II A	
	13	Ш	
Suture material, non absorbable Suture material, absorbable/medicated	7	ΠA	
	13	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	ПΑ	
Bleaching agents for intra dental bleaching professional use only	6	II A	
Impression materials	5	I	
		and the second s	

Cotton rolls, gauze, etc. 5 I Dental floss, medicated 13 IIII Wedges 5 I Waxes 5 I Retraction cords Retraction cords, medicated 13 IIII Note: Astringents and haemostatic solutions are medicinal products Matrix bands 5 I Impression trays 5 I Endodontic absorbant points 6 III A Polishing paste Polishing paste Polishing paste Polishing paste Polishing paste IIII Polishing strips 5 I Articulating, occlusion and bite registration devices 5 I Radiographic ITEN STANDARD PREVI W16 III A 2. Invasive devices, oral cavity, patient use dards. Iten. a) Denture adhesives, cushions and relining materials related to the control of III A Denture adhesives, cushions and relining materials related to the control of III A Denture adhesives, cushions and relining materials flows as College bits 5 II Temporary filling 6 III A Denture adhesives, cushions and relining materials 1 I Denture adhesives, cushions and relining materials 1 I A. Instruments Denture adhesives, cushions and relining materials 1 I A. Instruments Power operated instruments Dental handpieces for rotary instruments Dental handpieces for rotary instruments Power operated instruments Power operated instruments Power operated instruments Dental handpieces for rotary instruments Power operated instruments Powe			
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Hand operated instruments	Rotary instruments for connection to dental handpieces Surgically invasive Invasive (polishing and prophylactic devices)	6 5	II A II A
	Hand operated instruments		

Page 6 CR 12401:1996

Reusable	6	I
Single use	6	ПΑ
5. Equipment		
High and medium volume suction equipment	11	ПА
Dental unit incorporating, control or monitoring active devices in class II B	9	ΠВ
Dental unit incorporating, control or monitoring active device in class II A	9	ĤΑ
Dental operating light	12	Ĭ
Devices for disinfection of medical devices for dentistry	15	ПΑ
Cautery	9	ПВ
High frequency electrosurgery unit	9	ΠВ
Diagnostic fiberoptic handpieces	12	I
Laser unit dental, non surgical	9	ΠА
Laser unit dental, surgical	9	ПВ
Multifunctional syringe	11	ПА
Low voltage motor drive for handpieces (Standards.Iten.al)	9	II A
Air motor drive for handpieces SIST CR 12401:2000	9	II A
Dental patient chair https://standards.iteh.ai/catalog/standards/sist/6283eet3-bTac-4.	141-8167- 1	I
Dental curing light with handpieces	12	I
Pulp tester	10	ΠА
Dental radiographic equipment		ΠВ
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

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