# E ANSOCHMONT PEV **Dentistry - Reversible-irreversible** hydrocolloid impression material systems

Dentistry - Reversible-irreversible hydrocolloid impression material systems



# **EESTI STANDARDI EESSÕNA**

# **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 13716:2001 sisaldab Euroopa standardi EN ISO 13716:2000 ingliskeelset teksti.

Käesolev dokument on jõustatud 15.01.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 13716:2001 consists of the English text of the European standard EN ISO 13716:2000.

This document is endorsed on 15.01.2001 with the notification being published in the official publication of the Estonian national standardisation organisation.

The standard is available from Estonian standardisation organisation.

### Käsitlusala:

This standard specifies requirements and test methods for tensile bond strength and linear dimensional change of reversible-irreversible hydrocolloid impression materials used in dentistry, as well as requirements for their labelling and manufacturer's instructions.

# Scope:

This standard specifies requirements and test methods for tensile bond strength and linear dimensional change of reversibleirreversible hydrocolloid impression materials used in dentistry, as well as eq manu lice of the second of requirements for their labelling and manufacturer's instructions.

**ICS** 11.060.10

Võtmesõnad:

# **EUROPEAN STANDARD** NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 13716

August 2000

1.060.10

# **English version**

Dentistry – Reversible-irreversible hydrocolloid impression material systems

(ISO 13716: 1999)

Art dentaires – Systèmes de produits pour empreintes à base d'hydrocolloïdes réversibles-irréversibles (ISO 13716: 1999)

Zahnheilkunde - Reversible-irreversible Hydrokolloid-Abformmaterialiensysteme (ISO 13716: 1999)

This European Standard was approved by CEN on 2000-06-09.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, ain, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Page 2

EN ISO 13716: 2000

### **Foreword**

International Standard

ISO 13716: 1999 Dentistry - Reversible-irreversible hydrocolloid impression material systems,

which was prepared by ISO/TC 106 'Dentistry' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 55 'Dentistry', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by February 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

# **Endorsement notice**

The text of the International Standard ISO 13716: 1999 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

### **Contents**

NOTE: Normative references to international publications are listed in Annex ZA (n	ormative).
Contents	Page
1 Scope	
2 Normative references	3
3 Terms and definitions	3
4 Requirements	4
5 Sampling	4
6 Test methods — General	4
7 Tensile bond strength test	5
8 Linear dimensional change test	7
9 Information required in manufacturer's instructions	9
10 Requirements for labelling	
Bibliography	<b></b> 16

# Introduction

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this ISO Standard. But it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 7405 and ISO 10993-1.

# 1 Scope

This international Standard specifies requirements and test methods for tensile bond strength and linear dimensional change of reversible-irreversible hydrocolloid impression materials used in dentistry, as well as requirements for their labelling and manufacturer's instructions.

This international Standard is applicable to those alginate and syringeable agar dental impression materials which have been formulated such that they will bond to each other, when used in combination, to provide elastic impressions of oral tissues.

NOTE Requirements for other characteristics and properties of these impression materials are given in ISO 1563 and ISO 1564.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1563:1990, Dental alginate impression material.

ISO 1564:1995, Dental aqueous impression materials based on agar.

ISO 1942 (all parts), Dental vocabulary.

## 3 Terms and definitions

For purposes of this International Standard, the terms and definitions given in ISO 1942 and the following apply.

# 3.1

# bond

(between dental reversible and irreversible impression materials) adherence of the materials to each other after both materials have set

### 3.2

### storing

(of agar impression material) conditioning of the material, immediately after liquefaction, to reduce and maintain the temperature required for use in a succeeding step

### 3.3

### tensile bond strength

(of reversible-irreversible impression material specimen) force per unit area required to create a rupture in a specimen tested in the tensile mode