# Dentistry - Magnetic attachments (ISO 13017:2020)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD



| | |
|---|---|
| See Eesti standard EVS-EN ISO 13017:2020 sisaldab Euroopa standardi EN ISO 13017:2020 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 13017:2020 consists of the English text of the European standard EN ISO 13017:2020. |
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. |
| Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.07.2020. | Date of Availability of the European standard is 29.07.2020. |
| Standard on kättesaadav Eesti Standardikeskusest. | The standard is available from the Estonian Centre for Standardisation. |

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.060.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 13017

July 2020

ICS 11.060.10

Supersedes EN ISO 13017:2012

English Version

# Dentistry - Magnetic attachments (ISO 13017:2020)

Médecine bucco-dentaire - Attaches magnétiques (ISO 13017:2020)

Zahnheilkunde - Magnetische Retentionselemente (ISO 13017:2020)

This European Standard was approved by CEN on 27 June 2020.

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 CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**



Ref. No. EN ISO 13017:2020 E

## European foreword

This document (EN ISO 13017:2020) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2021, and conflicting national standards shall be withdrawn at the latest by January 2021.

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

This document supersedes EN ISO 13017:2012.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 13017:2020 has been approved by CEN as EN ISO 13017:2020 without any modification.

# Contents

Page

# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*. This second edition cancels and replaces the first edition (ISO 13017:2012), which has been technically revised. It also incorporates the Amendment ISO 13017:2012/Amd.1:2015. The main changes compared to the previous edition are as follows:

— addition of ISO 14233 to Clause 2;

— addition of lead as a hazardous element;

— addition of the cleaning method of test specimens prepared for retentive force;

— change of the device for retentive force to a single shaft type;

— change of Figure 3 to the single shaft type device;

— specification of the performance of the device with respect to moving friction force and modification of specimen tables;

— change of a cross-head speed in measuring retentive force from 5,0 mm $min^{-1}$ to 2,0 mm $min^{-1}$;

— addition of materials for fixing a specimen on the table such as cyanoacrylate adhesive and self-curing acrylic resin;

— deletion of the description of the adhesive double sided tape to fix a specimen on the table;

— specification of the procedures to fix a specimen on the table;

— addition of detailed method of measuring retentive force;

— addition of explaining the calculation method of retentive force;

— addition of a figure that shows a retentive force curve as Figure 4;



 

— specification of quantitative analyses in the static immersion test using definition of determination limit and detection limit;

— addition of “quantity” to labelling.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

The early practical uses of permanent magnets were as navigational compasses. Magnets have since become firmly integrated into today's modern electronic device technology. The development of magnetic technology has generated rare earth magnets. Their excellent magnetic character properties permit predictable clinical applications and use. Dental magnetic attachments are one of the products composed of rare earth magnets, providing retention, support and stabilization of dental and maxillofacial appliances.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document, but for the assessment of possible biological or toxicological hazards, reference can be made to ISO 10993-1 and ISO 7405.

# Dentistry — Magnetic attachments



## 1 Scope

This document specifies requirements and test methods for assessing the applicability of dental magnetic attachments that provide retention, support and stabilization of removable prostheses (crowns and bridges, partial dentures and overdentures), superstructures of dental implants and orthodontic or maxillofacial prostheses including obturators.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3585, *Borosilicate glass 3.3 — Properties*

ISO 5832-1, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*

ISO 10271, *Dentistry — Corrosion test methods for metallic materials*

ISO 14233, *Dentistry — Polymer-based die materials*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 22674, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

IEC 60404-8-1, *Magnetic materials — Part 8-1: Specifications for individual materials — Magnetically hard materials*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 10271 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

**3.1**
**magnetic attachment**
device to provide retention of a prosthesis mainly utilizing magnetic attraction

**3.1.1**
**open magnetic circuit attachment**
*magnetic attachment* (3.1) wherein a magnetized permanent magnet is working by itself with no high permeability material

Note 1 to entry: The magnet is encased within a corrosion-resistant metal or alloy cover of titanium, titanium alloy or stainless steel to prevent corrosion of the magnet. The attachment uses either a magnet and a ferromagnetic alloy *keeper* (3.3) or two magnets as retentive coupling components.