



NSAI
Standards

Irish Standard
I.S. EN ISO 13017:2012&A1:2015

Dentistry - Magnetic attachments (ISO 13017:2012)

I.S. EN ISO 13017:2012&A1:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

EN ISO 13017:2012/A1:2015

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SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

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National Foreword

I.S. EN ISO 13017:2012&A1:2015 is the adopted Irish version of the European Document EN ISO 13017:2012, Dentistry - Magnetic attachments (ISO 13017:2012)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPEAN STANDARD

EN ISO 13017:2012/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2015

ICS 11.060.10

English Version

Dentistry - Magnetic attachments - Amendment 1 (ISO 13017:2012/Amd 1:2015)

Médecine bucco-dentaire - Attaches magnétiques -
Amendement 1 (ISO 13017:2012/Amd 1:2015)

Zahnheilkunde - Magnetische Retentionselemente -
Änderung 1 (ISO 13017:2012/Amd 1:2015)

This amendment A1 modifies the European Standard EN ISO 13017:2012; it was approved by CEN on 3 October 2015.

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This amendment 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.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

EN ISO 13017:2012/A1:2015 (E)

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European foreword

This document (EN ISO 13017:2012/A1:2015) 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 Amendment to the European Standard EN ISO 13017:2012 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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Endorsement notice

The text of ISO 13017:2012/Amd 1:2015 has been approved by CEN as EN ISO 13017:2012/A1:2015 without any modification.

EUROPEAN STANDARD

EN ISO 13017

NORME EUROPÉENNE

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July 2012

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English Version

Dentistry - Magnetic attachments (ISO 13017:2012)

Médecine bucco-dentaire - Attaches magnétiques (ISO
13017:2012)

Zahnheilkunde - Magnetische Befestigungselemente (ISO
13017:2012)

This European Standard was approved by CEN on 14 July 2012.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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EN ISO 13017:2012 (E)

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Foreword

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Endorsement notice

The text of ISO 13017:2012 has been approved by CEN as a EN ISO 13017:2012 without any modification.

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INTERNATIONAL STANDARD

**ISO
13017**

First edition
2012-07-15

Dentistry — Magnetic attachments

Médecine bucco-dentaire — Attaches magnétiques



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 13017 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

ISO 13017:2012(E)

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.

Dentistry — Magnetic attachments

1 Scope

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

This International Standard does not specify qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risk, which can be assessed using ISO 10993-1 and ISO 7405.

2 Normative references

The following referenced documents are indispensable for the application 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 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*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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 and the following apply.

3.1

magnetic attachment

device to provide retention of a prosthesis utilizing magnetic attraction as shown in Figures 1 and 2

3.1.1

open magnetic circuit attachment

magnetic attachment which utilizes an open magnetic circuit between coupled components

NOTE 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, and utilizes the attractive force between either two magnets or between a magnet and a ferromagnetic alloy keeper as retentive coupling components.

See Figure 1.

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