

Dentistry - Magnetic attachments (ISO 13017:2012)

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NATIONAL FOREWORD

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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)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN ISO 13017:2012) 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of an identical text or by endorsement, at the latest by January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

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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.

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.