

ICS 11.060.10
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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1637-2025

Replacing YY/T 1637-2018

Dentistry - Magnetic attachments

牙科学 磁性附着体

(English Translation)

Issued on: October 30, 2015

Implemented on: November 1, 2026

Issued by: National Medical Products Administration

Table of Contents

- Foreword
- 1 Scope
- 2 Normative references
- 3 Terms and Definitions

Foreword

This document conforms to GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting is scheduled.

This document replaces YY/T 1637-2018 "Magnetic Attachments in Dentistry". Compared with YY/T 1637-2018, the only changes are structural adjustments.

Aside from editorial changes, the main technical changes are as follows.

- The inclusion of lead as a hazardous element has been added (see 4.2.1).
- Added a cleaning method for the retention force test samples (see 5.1);
- Change the retaining force device to a single tie rod type (see 6.3.1.2);
- The single-lever mechanism has been modified (see Figure 3);
- Changes were made to the properties of the apparatus regarding moving friction and the sample stage (see 6.3);
- Change the crosshead speed under retaining force from 5.0 mm/min to 2.0 mm/min (see 6.3.1.1);
- Materials for fixing the specimens on the platform have been added, such as cyanoacrylate adhesive and self-curing acrylic resin (see 6.3.2).
- The description of the double-sided tape used to fix the sample to the platform has been deleted (see 6.3.2.1 in the 2018 version).
- The procedure for fixing the sample on the platform has been changed (see 6.3.3);
- Added a detailed method for measuring retention force (see 6.3.4);
- Added explanation of the calculation method for retention force (see 6.3.5);
- Figure 4 has been added to show the retention force curve;

--The quantitative analysis of the static immersion test was modified by defining the limit of verification and the limit of detection (see 6.4.1.5).

--Added "Quantity" to the identifier (see 8.2).

This document is modified to adopt ISO 13017:2020 "Dental Science - Magnetic attachments".

The technical differences between this document and ISO 13017:2020, and the reasons therefor, are as follows.

This document specifies the requirements and test methods for dental magnetic attachments, which are used for crowns and bridges, removable implants, etc.

It provides retention and support for prostheses such as partial dentures, overdentures, implant superstructures, and orthodontic and maxillofacial prostheses (including obstrutors).

The phrase "support and stability" should be changed to "This document specifies the requirements and test methods for dental magnetic attachments, which are used for...".

It provides retention and support for removable partial dentures, overdentures, implant superstructures, and maxillofacial prostheses (including obturators).

Support and stability. The reason is that magnetic attachments have never been used clinically in the areas of fixed restorations, specifically in "crowns and bridges" and "orthodontics." (See Chapter 1).

--Change "The main components of the magnetic core should meet the main component requirements of IEC 60404-8-1 Magnet Classification" to "Should use components that meet the requirements of..." GB/T 17951 classifies magnetic materials by their main components as magnetic cores. The reason for this is that the composition of the magnet is not restricted, so as not to hinder the production of...

Product innovation (see 4.1.1).

--Change "The main elements of the magnetic core shall comply with the provisions of GB/T 17951 (see 7a)" to "The manufacturer shall declare the main elements of the magnetic core." it conforms to GB/T 17951 (see 7a). A note is added. "Note. The main elements of the magnetic nucleus conform to GB/T 17951, referring to element..." it conforms to GB/T 17951, not the content. The reason is not to restrict the composition of the magnet, so as not to hinder product innovation (see 4.1.3).

--The breakdown voltage of the magnet or combination magnet with armature shall be equal to or higher than the breakdown voltage of the stainless steel workpiece specified in ISO 58321.

The wording should be changed from "Voltage" to "The breakdown voltage of the magnet or

combination of magnets and armature should not be lower than the value claimed in the manufacturer's instructions." This is because ISO 58321...

No breakdown voltage value is specified for any material (see 4.6.2).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Dental Materials and Instruments (SAC/TC 99).

1 Scope

This document specifies the requirements for dental magnetic attachments and describes the corresponding test methods.

Dental magnetic attachments are suitable for removable partial dentures, overdentures, implant superstructures, and maxillofacial prostheses (including obstructors).

The prosthesis provides retention, support, and stability.

This document does not include qualitative or quantitative requirements for potential biological hazards, but it is recommended that when assessing potential biological hazards, refer to [the relevant documentation/reference].

Refer to GB/T 16886.1 and YY/T 0268.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB 4234.1 Metallic materials for surgical implants - Part 1: Forged stainless steel (GB 4234.1..2017, ISO 5832-1.

2007, MOD)

GB/T 9937 Terminology in Dentistry (GB/T 9937-2020, ISO 1942-2009, MOD) GB 17168 Metallic materials for fixed and removable dental restorations (GB 17168.2013, ISO 22674:2006, IDT) GB/T 17951 General technical conditions for hard magnetic materials (GB/T 17951.2022, IEC 60404-8-1:2015, MOD) GB/T 27025 General requirements for the competence of testing and calibration laboratories (GB/T 27025-2019, ISO/IEC

17025:2017) IDT YY/T 0316 Application of Risk Management to Medical Devices (YY/T 0316-2016, ISO 14971:2007) IDT YY/T 0466.1 Symbols for medical devices used to provide information to manufacturers - Part 1: General requirements (YY/T 0466.1-2023, ISO 15223-1:2021, MOD) YY/T 0528 Test methods for corrosion of metallic materials used in dentistry (YY/T 0528-2018, ISO 10271:2011, IDT) YY/T 0911 Dental polymer-based substitute materials (YY/T 0911-2014, ISO 14233:2003, IDT) HG/T 3115 Borosilicate Glass 3.3 Characteristics (HG/T 3115-1998, ISO 3585:1991, IDT)

3 Terms and Definitions

The terms and definitions defined in GB/T 9937 and the following terms and definitions apply to this document.

Magnetic attachment

A device that uses magnetic force to retain the prosthesis.

3.1.1

Open magnetic circuit attachment A magnetic attachment that generates magnetic force by utilizing an open magnetic circuit between two pairs of components.

Note: To prevent corrosion of the magnet, it will be encased in a shell made of a corrosion-resistant metal or alloy such as pure titanium, alloy, or stainless steel.

A dual-component assembly held in place by the attractive force between two magnets or between a single magnet and a ferromagnetic alloy armature. See Figure 1.