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

YY/T 2009-2026

**In vitro degradation test method of biodegradable
magnesium-based implants**

可降解镁基金属植入物体外降解试验方法

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. This document is published. The organization is not responsible 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/TC99). This document was drafted by: the Center for Dental Medical Device Testing, Peking University School of Stomatology; Peking University School of Stomatology; and Zhejiang Fengyuan Biotechnology. Technology Co., Ltd., Sichuan University, Ninth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Institute of Metal Research, Chinese Academy of Sciences, Guangzhou Medical University Affiliated Stomatological Hospital of the University, and Shanghai Innovation Medical Technology (Shanghai) Co., Ltd. The main drafters of this document are. Guo Chuanbin, Han Jianmin, Zhu Jianhua, Wan Ziyi, Liu Zhichao, Liu Guanqi, Yuan Tun, Liu Xin, Yang Ke, and Sui Baiyan. Deng Xiang, Lu Hua, Zhang Jian, Li Ping. In vitro degradation test method for degradable magnesium-based metal implants

1 Scope

YY/T 2009 is the bench method for a class of implant designed to disappear. It describes the method for evaluating the in vitro degradation of oral biodegradable magnesium-based metal implants, made of pure magnesium or a magnesium alloy. Magnesium implants are meant to corrode away once the bone has healed, so their degradation rate is the primary performance characteristic rather than a durability concern, and it has to be measured under conditions that stand in for the oral environment. The standard sits with the dental corrosion methods it cites, including YY/T 0528 and YY/T 0695. For a manufacturer

developing resorbable magnesium screws, plates or membranes for dental and maxillofacial use, this is the test a Chinese reviewer expects behind the degradation claim.

This document describes a method for evaluating in vitro degradation tests of oral biodegradable magnesium-based metal (pure magnesium or magnesium alloy) implants. This document applies to the in vitro degradation determination of oral biodegradable magnesium-based metal (pure magnesium or magnesium alloy) implants.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. 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/T 6682 Specifications and test methods for water used in analytical laboratories

GB/T 9937 Terminology in Dentistry

GB/T 10123 Corrosion Terminology for Metals and Alloys

GB/T 26497-2022 Electronic Balance

YY/T 0528 Dental Corrosion Test Methods for Metallic Materials

YY/T 0695 Standard Test Method for Cyclic Potential Polarization of Corrosion Sensitivity of Small Implantable Instruments

HG/T 3115 Performance of Borosilicate Glass

3 Terms and Definitions

The terms and definitions defined in GB/T 9937, GB/T 10123, and YY/T 0528, as well as the following terms and definitions, apply to this document.

3.1 Electrolyte A medium that transmits electric current through ions. [Source: GB/T 10123-2022, 7.1.1]

3.2 An electrochemical measurement method that uses a small-amplitude sinusoidal potential (or current) as a perturbation signal.

4.1 Hydrogen evolution test

4.1.1 Appliances Borosilicate glass containers conforming to HG/T 3115; Balances conforming to GB/T 26497 with a verification value $e \leq 1$ mg; Water that meets the GB/T 6682 standard (Grade II).