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

YY 0300-2025

Replacing YY 0300-2009

Dentistry - Artificial teeth for dental prostheses

牙科学 修复用人工牙

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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. This document replaces YY 0300-2009 "Dental Prosthetics". Compared with YY 0300-2009, the main differences are in the structural adjustments and compilation. Aside from the logical changes, the main technical changes are as follows:

---The section on "Terms and Definitions" now includes the URLs for the ISO and IEC databases of maintenance terminology for standards (see Chapter 3);

---The term "artificial teeth" has been added to the "Terms and Definitions" section (see 3.1). This document is modified to adopt ISO 22112.2017 "Dental science - Artificial teeth for restorative purposes". Compared with ISO 22112.2017, this document has undergone the following structural adjustments.

---The description of

5.1.1 biocompatibility has been moved to the introduction, and the article numbers in Chapter 5 have been adjusted accordingly. The technical differences between this document and ISO 22112.2017, and the reasons therefor, are as follows:

--- An experimental method for multi-layered tooth boundary lines has been added (see 7.3.2.2). 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/TC99). The release history of this document and the document it replaces is as follows:

---First published as GB 8265-1987 and GB 7110-1986;

---In the first revision in 1998, they were adjusted to YY 0300-1998 and YY 0301-1998 respectively;

---In the second revision in 2009, it was merged and adjusted to YY 0300-2009;

---This is the third revision.

This document does not include specific qualitative and quantitative test methods to demonstrate the absence of unacceptable biohazards, but recommends them in assessing potential biological hazards. When hazards are involved, refer to ISO 10993-1 and ISO 7405. Dental prostheses

1 Scope

YY 0300 is the mandatory standard for the artificial tooth used in dentures and other dental prostheses. It specifies the classification and requirements for polymer teeth and ceramic teeth used in dental restorations and describes the corresponding test methods, applying to synthetic resin teeth and ceramic teeth. Denture teeth are a high-volume, low-unit-cost product where the properties that matter, wear resistance, bond to the denture base, colour stability and dimensional consistency across a mould set, are easy to compromise and hard for a dentist to assess on receipt, which is the case for keeping the standard compulsory. The YY prefix without /T makes compliance mandatory in China, and the 2025 edition takes effect on 1 July 2028. For any manufacturer or importer of denture teeth, this is the governing document.

YY/T 0462 Dental plaster products (YY/T 0462-2018, ISO 6873.2013, MOD)

YY/T 0631-2008 Determination of color stability of dental materials (ISO 7491.2000, IDT)

Note. The content referenced in

YY/T 0631-2008 is not technically different from the content referenced in ISO 7491.2008.

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 9937 Terminology in Dentistry (GB/T 9937-2020, ISO 1942.2009, MOD)

GB 9938-2013 Dental marking of tooth positions and oral regions (ISO 3950.2009, IDT)

YY 0270.1-2011 Dental base polymers - Part

ISO 483 Plastics - Small, airtight containers for use in conditioning and testing with aqueous solutions to maintain constant humidity. value) ISO 6344-

3 Terms and Definitions

The terms and definitions defined in GB/T 9937 and YY 0270.1-2011, as well as the following terms and definitions, apply to this document. The URLs for the terminology databases maintained by ISO and IEC for standardization are as follows:

3.1 artificial teeth Products designed to mimic and replace natural teeth.

3.2 perforated teeth diatoricteeth Teeth that are retained by retention grooves and/or hole structures.

3.3 pinteeth Teeth secured by nails.