

ICS 11.060.10
CCS C33

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

YY/T 1937-2024

Customized removable denture

定制式活动义齿

Issued on: July 8, 2024

Implemented on: July 20, 2025

Issued by: National Medical Products Administration

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Dental Materials, Instruments and Equipment (SAC/TC99). This document was drafted by: West China School of Stomatology, Sichuan University, and Peking University School of Stomatology. The main drafters of this document are: Yue Li, Yu Haiyang, Zheng Liwei, Hu Xiaoyang, Zheng Gang, Lin Hong, Yan Chunxi, Bai Wei, Zhang Na, Dong Bo, Zhou Min.

The main technical indicators of this document are determined based on actual clinical usage. In theory, the laboratory tests in the appendix to this document also need to consider the following factors: functionality, durability and tear resistance, the development of new materials. The impact of these factors on the environment and the activities of users as part of the assessment process. Needs to be constantly replenished. Since this document stipulates that the raw materials used in customized removable dentures must have obtained a medical device product registration certificate, this document will no longer involve Evaluation of biocompatibility. There are many methods for testing the internal quality of metals. Appendix B of this document lists other methods for testing the internal quality of metals for reference. However, these methods have their own limitations when

used for internal quality inspection of customized denture metal. With the development of metal internal quality inspection methods, new inspection methods may be replaced by new inspection methods. Customized removable dentures

1 Scope

YY/T 1937 is the product standard for the custom-made removable denture, a device that is designed and manufactured for one named patient and therefore never goes through the type testing that a mass-produced device does. That is the regulatory problem custom device standards exist to solve: the requirements attach to the materials, the process and the documentation rather than to a finished article that can be sampled. It covers the partial and complete removable prostheses produced by dental laboratories, and it is the removable counterpart of YY/T 1936 on custom fixed prostheses, issued the same day. For a dental laboratory serving the Chinese market, or a manufacturer supplying the materials and digital workflow behind one, this is the standard the production and records are assessed against.

This document specifies the requirements for custom-made removable dentures and describes the corresponding test methods. This document applies to custom-made removable dentures.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 9937-2020 Dental terminology

GB 17168-2013 Metal materials for fixed and removable restorations in dentistry

YY 0270.1-2011 Dental base polymers Part

3 Terms and definitions

The terms and definitions defined in GB/T 9937-2020 and the following apply to this document.

3.1 Customized denture customizeddenture Denture manufacturers use dental materials to carry out restoration design and production according to the patient model and the requirements of the design sheet. Medical institutions provide restorations that can restore the morphology, function and aesthetics of patients' tooth defects, edentulous spaces and missing teeth.

Note. Includes customized fixed dentures and customized removable dentures.

3.2 Restoration Dental medical devices used to restore or replace missing tooth structure, teeth or oral tissue.

3.3 It is used to repair the patient's tooth defects or missing teeth, using the natural teeth and the mucosa and bone tissue covered by the base as support, using the retainer and base The restoration is well-retained and can be removed and put on by the patient.

Note. Includes removable partial dentures and complete dentures.

3.4 A removable denture that replaces only some of the teeth in one arch, but not all of them.

3.5 Complete denture Removable dentures for maxillary or mandibular edentulous patients.