

ICS 11.060.10
CCS C33

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

YY/T 1936-2024

Customized fixed prosthesis

定制式固定义齿

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 and Instruments (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: Yu Haiyang, Yue Li, Zheng Liwei, Yu Na, Hu Xiaoyang, Lin Hong, Zheng Gang, Yan Chunxi, Bai Wei, Zhang Na, Ren Wei, Zhou Min.

The main technical indicators of this document are determined based on long-term clinical experience. 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 fixed dentures must have obtained a medical device product registration certificate, this document will no longer involve Evaluation of biocompatibility. Considering that some denture manufacturers currently produce custom fixed dentures, the crown and bridge base (including metal base and zirconia base) The crown and bridge base is shipped as the final product, therefore,

this document incorporates the requirements for the crown and bridge base. 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 fixed dentures

1 Scope

YY/T 1936 is the product standard for the custom-made fixed dental prosthesis: the crowns, bridges and cemented restorations made to one patient's impression or scan. Like its removable counterpart YY/T 1937, it addresses a device that cannot be type tested because each unit is unique, so the requirements bear on the materials used, the manufacturing process and the records that link a finished restoration back to the prescription and the batch of material it came from. Digital design and milling have made the process reproducible in a way it was not, which is precisely what makes standardising it possible. For a dental laboratory or a milling centre serving the Chinese market, this is the standard the production system and documentation are assessed against.

This document specifies the requirements for custom-made fixed dentures and describes the corresponding test methods. This document is applicable to customized fixed dentures and crown and bridge bases (including metal bases and zirconia bases) shipped as products.

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

GB 30367-2013 Dental ceramic materials

YY 0300-2009 Artificial teeth for dental restoration

YY/T 0462-2018 Dental plaster products

YY 0621.1-2016 Dental matching test 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. Providing medical institutions with restorations that can restore the morphology, function and aesthetics of patients' tooth defects, edentulous 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 fixed in the patient's mouth by bonding or other retention forces. Once the restoration is put in, the patient cannot take it off by himself. Dentures.

3.4 fixed bridge Use the natural teeth near and far from the missing teeth as abutments to repair one or more missing natural teeth in the dentition defect and restore its anatomical shape. and physiological function of fixed dentures.