ICS 11.060.10
CCS C33

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1932-2024

Dentistry - Bracketless orthodontic aligner

牙科学 膜片式无托槽正畸矫治器

Issued on: July 8, 2024 **Implemented on: July 20, 2025**

Issued by: National Medical Products Administration

Table of Contents

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: Oral Medical Device Testing Center, Peking University School of Stomatology, Shanghai Angelalign Medical Devices Co., Ltd., Sichuan Medical Device Biomaterials and Products Inspection Center Co., Ltd. The main drafters of this document are. Bai Wei, Li Huamin, Huang Lei, Zheng Yikan, Lin Hong, Cheng Dongqin and Wu Minhua.

Diaphragm-type bracketless orthodontic appliances are made of thermoplastic polymer diaphragms, which are processed by heating and pressurizing on the patient's tooth model. Used for orthodontic treatment of patients' dental deformities. Since the membrane type bracketless orthodontic appliance is usually made on a 3D printed dental model, this document only In addition to stipulating the general requirements for brackets and orthodontic appliances, it also sets requirements for 3D printed dental models that affect their quality. This document does not include qualitative and quantitative test methods for demonstrating that materials do not present an unacceptable biological risk, such as the assessment of such biological Risks can be referred to GB/T 16886.1 and YY/T 0268. This document does not include regulations on the monitoring of the entire medical-engineering interaction process of diaphragm-type bracketless orthodontic appliances and the determination of indicators and acceptance conditions. Dental diaphragm bracketless orthodontic appliance

1 Scope

YY/T 1932 is the product standard for the clear orthodontic aligner, the thermoformed shell that has largely displaced fixed braces in adult orthodontics and that China manufactures in enormous volume. It covers the bracketless aligner made from sheet material, a device that is custom-made for one patient and delivered as a numbered series, each shell moving the teeth a fraction of a millimetre further than the last. The properties that decide whether the treatment works are material ones, the force the shell delivers and how it decays over the wear period, together with dimensional fidelity to the digital plan and the biological safety of a device worn twenty-two hours a day. For a manufacturer or an importer of aligner systems seeking Chinese registration, this is the governing product standard.

This document specifies the performance requirements, tests and Evaluation methods, labeling and product instruction manual information. This document applies to diaphragm-type bracketless orthodontic appliances.

Note. In order to avoid confusion, "diaphragm-type bracketless orthodontic appliance" in this document is referred to as "appliance".

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 6682 Specifications and test methods for water used in analytical laboratories

GB/T 9937 Dental terminology

GB/T 14233.1-2022 Inspection methods for medical infusion, blood transfusion and injection equipment Part

3 Terms and definitions

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

3.1 A series of custom-made braces made of thermoplastic polymer membranes, which are worn on the teeth and the membranes rebound to shift the teeth, thereby achieving Removable orthodontic appliances for treating dental malocclusion. 3.2 3D-printeddentalmodel A model made of resin material through additive manufacturing (3D printing) with the same shape as the patient's jaw shape. Used as a diaphragm for hot pressing Molding mold.

3.3 Initial holding force initial holding force The initial pressure applied to the diaphragm-type bracketless orthodontic appliance specimen using a pressure-generating fixture.

3.4 A continuous pressure is applied to the specimen of the diaphragm-type bracketless orthodontic appliance using a pressure-generating fixture.

3.5 Anti-stain property The ability of diaphragm-type bracketless orthodontic appliances to resist staining when in contact with colored drinks or foods.