

ICS 11.060.10

CCS B64

YY

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

YY/T 1886-2023

Dentistry - Pre-capsulated dental amalgam

牙科学 胶囊装银汞合金

Issued on: January 13, 2023

Implemented on: January 15, 2024

Issued by: National Medical Products Administration

Table of Contents

Foreword

1 Scope

2 Normative references

3 Terms and definitions

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. This document is modified to adopt ISO 20749.2017 "Silver Amalgam in Capsules in Dentistry". The technical differences between this document and ISO 20749.2017 and their reasons are as follows:

---In "Properties of dental amalgam", change "1h minimum compressive strength 100MPa" to "1h minimum compressive strength 80MPa" (see 4.7), to adapt to the actual situation of existing products in our country;

---In "Mass loss of capsules during blending" put "average mass loss of dental mercury and dental silver alloy powder in 15 capsules (mixed according to manufacturer's instructions) not to exceed

0.5 mg" changed to "dental mercury and dental silver alloy in 5 capsules The average mass loss of the powder (reconciled according to the manufacturer's instructions) shall not exceed

0.5 mg" (see 4.4) to better protect The environment and the health of testing personnel. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Standardization Technical Committee on Dental Materials and Devices (SAC/TC99). This document is drafted by: Peking University School of Stomatology Dental Medical Device Inspection Center, Shanghai Medical Devices Co., Ltd. Dental Materials Material factory. The main drafters of this document. Yuan Shenpo, Lin Hong, Sun Zhihui, Du Zumin, Bai Wei, Zhang Dianyun.

This document applies only to dental silver alloy powder and dental mercury in capsules of a certain quality, dental silver alloy powder and dental mercury in individual capsules. Dental amalgam prepared with Komermal is sufficient for the restoration of individual small or medium-sized restorations of individual teeth. Dental silver alloy powder and dental

mercury are essential components of dental amalgam restorative materials. This document has been prepared in accordance with the United Nations Environment Programme's Minamata Convention on Mercury. The objective of the Minamata Convention on Mercury is to adopt Reduce anthropogenic mercury pollution by restricting the use of mercury, mercury-containing products, and materials that release mercury during use. In this convention, dental amalgamation Gold is classified as a "mercury-added product", for which the parties to the agreement should take two or more measures from List IX. One of them is "Dental Silver Amalgam restricted to use in encapsulated form". In some countries, the term "encapsulated" is interpreted only as pre-encapsulated form. Since the signing of the Minamata Convention on Mercury in Countries that allow the use of prepackaged products are able to adopt standards for dental amalgam. Although this document is formulated based on YY/T 1026, major technical requirements have been changed. In addition, YY 0715 middle rubber The requirements of the package are also incorporated into this document, and the products to which this document applies are considered as a whole. This document and the specific technical requirements of YY/T 1026 Change as follows:

- This document is only applicable to pre-capsulated dental amalgam products.
- This document makes requirements for the pollution-free capsules and packaging.
- This document deletes the requirements for foreign matter in dental silver alloy powder.
- This document increases the requirements for the mass loss of capsules during the blending process.
- This document replaces the requirements for the quality of dental mercury and silver alloy powder before blending with the requirements for the output of amalgam in capsules.
- This document has fundamentally changed the requirements for consistency in the ratio of dental mercury to silver alloy powder in capsules. changed to Determination of the effect of changes in this ratio on performance is used instead of weighing mercury and silver alloy powders.
- This document introduces the requirements for capsules and makes technical revisions to it. This document makes no changes to the requirements not related to packaging, which are.

1 Scope

YY/T 1886 covers dental amalgam supplied in pre-dosed capsules, the form in which the alloy and the mercury are sealed together and mixed in the surgery rather than handled loose. It sets the requirements such a capsule has to meet and the test methods that verify them, covering the composition of the alloy, the mechanical properties of the set restoration, the behaviour of the capsule during trituration and the containment that keeps mercury out of the operator air. Capsulation exists precisely to control mercury exposure,

so the integrity of the capsule is as much a part of the specification as the strength of the filling. Amalgam remains in wide use in Chinese public dentistry even as it is phased down elsewhere. This is the document a manufacturer certifies against to register the product in China.

2 Part. Characterization of Height Characteristics by Linearized Support Ratio Curve (GB/T 18778.2-2003, ISO 13565-2.1996, IDT)

YY/T 0466.1-2016 Symbols for Medical Device Labeling, Marking and Information Provision for Medical Devices Part

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references Only the version corresponding to that date applies to this document. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 1800.2 Product Geometric Specifications (GPS) Linear Dimensional Tolerances ISO Code System Part

2.Standard Tolerance Zones Code and limit deviation table of holes and shafts (GB/T 1800.2-2020, ISO 286-2.2010, MOD)

GB/T 2893.2 Graphical symbols, safety colors and safety signs - Part

2.Design principles for product safety labels (GB/T 2893.2-2020, ISO 3864-2.2016, MOD)

GB/T 6003.1 Test sieve technical requirements and inspection Part

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

GB/T 18778.2 Product Geometric Quantity Specifications (GPS) Surface Structure Profile Method Surfaces with Composite Machining Features No.