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

YY/T 0462-2018

**Dentistry-Gypsum products
(English Translation)**

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Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

This standard replaces YY 0462-2003 "Dental Gypsum Products":

Compared with YY 0462-2003, the technical changes of this standard are as follows: These changes are caused by the changes of ISO 6873:2013:

--- Chapter 1 "Scope" added "This standard does not apply to dental bone substitutes composed of calcium sulfate hemihydrate (or gypsum)";

--- Added Chapter 2 "Normative References", and the numbers of subsequent chapters were changed accordingly;

---Chapter 3 "Terms and Definitions" added "GB/T 9937.1-2008, GB/T 9937.2-2008, GB/T 9937.3-2008, Defined by GB/T 9937.4-2005 and GB/T 9937.5-2008";

---Chapter 4 "Classification" is changed to:

- a) Type 1: dental impression plaster;
- b) Type 2: dental fixed plaster (category 1) and cast cast (category 2);
- c) Type 3: artificial stone for dental models;
- d) Type 4: Dental (high-strength, low-expansion) artificial stone, model base and CAD/CAM (computer-aided design and manufacturing) Made) generation;
- e) Type 5: Dental (high-strength, high-expansion) substitute artificial stone, high-expansion compensates for some materials used in dental restorations shrink:

---The original 4:1 "Appearance" was changed to 5:1 "Quality";

---5.3 "curing time" added "marked value on product packaging";

---5.4 "Line curing expansion" adds 0.00%~0.05% of type 2 (type 1) gypsum line curing

expansion, type 2 (2 types) gypsum line curing expansion Expansion of 0.06%~0.30%, line curing expansion of type 4 gypsum for 24 hours is 0.00%~0.18%;

--- 6.1 "Sampling", add "retail products before packaging suitable for the products provided";

--- 7.1 "Visual inspection", added "Check whether the provided packaging, labels and information meet the requirements of Chapter 8";

--- 7.2.1.3 Added "apparatus for measuring the length of 35mm~100mm";

--- Added 7:3:1:2:2 "Small cylindrical mold", and "Note: In order to effectively utilize resources, small molds can be used instead of traditional large molds:

Users should understand that the smaller the area, the fewer indentation points are allowed (according to 7:3:2), and special attention should be paid to the timing of the first needle insertion:

time (related to the expected curing time)";

--- Added 7:3:1:3 "release agent";

--- Modified 7:3:2 "Test procedure", adding the test method and test precautions for the small cylindrical mold;

--- 7.3.3 "Evaluation" has been modified, and Type 1 products are evaluated separately from Type 2, Type 3, Type 4, and Type 5 products;

--- In 7:4:1 "Apparatus", the triangular cross-section groove was modified, and 7:4:1:1:2 "square cross-section groove" was added, and Figure 3, Figure 4,

Figure 5;

--- In 7:4:2 "Procedures", the calculation method of the test results in 7:4:2:1 "Triangle cross-section groove" is modified, and 7:4:2:2 "Square cross-section "Trough" test method;

--- In 7:4:3 "Evaluation", the 24h measurement results of type 4 materials are added;

---In 7:6:2 "step", change the mass of gypsum from 300g to (200±1)g;

--- Added 7:7:1:8 "Talc powder";

--- 8.2.1 Added "recommended water/powder ratio", "curing time", "curing expansion" and "if graphic symbols are used, they shall comply with Combined with YY/T 0466.1-2016";

---The original 7:2:2 "inner packaging" was changed to 8:2:2 "independent packaging";

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---The original 7:3 "Information provided by the manufacturer" was changed to 8:3 "Instructions for use";

---Delete the original 7:4 "Chinese logo":

This standard uses the redrafted method to revise and adopt ISO 6873:2013 "Dentistry Gypsum Products":

The technical differences between this standard and ISO 6873:2013 and their reasons are as follows:

--- Regarding the normative reference documents, this standard has made adjustments with technical differences to adapt to the technical conditions of our country and the adjustment situation the situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows:

- Replaced ISO 1302:2002 with GB/T 131-2006, which is equivalent to the international standard;
- Replaced ISO 3696:1987 with GB/T 6682-2008, which adopts international standards;
- Replaced ISO 8601:2000 with GB/T 7408-2005, which is equivalent to the international standard;
- Use GB/T 9937 (all parts) to replace ISO 1942 (all parts), the degree of consistency between the parts of the two standards as follows:

* GB/T 9937.1-2008 Oral Vocabulary Part 1: Basic and Clinical Terms (ISO 1942-1:1989, IDT) * GB/T 9937.2-2008 Oral vocabulary Part 2: Oral materials (ISO 1942-2:1989, IDT) * GB/T 9937.3-2008 Oral Vocabulary Part 3: Dental Devices (ISO 1942-3:1989, IDT) * GB/T 9937.4-2005 Dental Terminology Part 4: Dental Equipment (ISO 1942-4:1989, IDT) * GB/T 9937.5-2008 Oral vocabulary Part 5: Terms related to testing (ISO 1942-5:1989, IDT) - Replace ISO 15223-1 with YY/T 0466.1, which is equivalent to the international standard:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by the State Drug Administration:

This standard is under the jurisdiction of the National Dental Materials and Devices Standardization Technical Committee (SAC/TC99):

Introduction

Since the publication of the previous edition of ISO 6873, some properties of plaster products already on the market (required for newly introduced dental techniques) are no longer Some requirements specified in this edition of the standard apply, therefore, this revision is made: In this version, the classification has been modified, and the relevant requirements have also been revised:

Appropriate modifications were made: In addition, considering that the type 4 dental artificial stone used to make CAD/CAM models should not produce obvious However, the

previous version only gave the requirements for curing expansion at 2 hours: This version stipulates that type 4 materials also need to be tested at 24 hours:

Cure expands and gives requirements:

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Dental plaster products

1 Scope

This standard specifies the classification and performance requirements of gypsum products used in dentistry, the test methods for relevant requirements, packaging labels and instructions for use book request:

This standard applies to the production of oral impressions, models, casting models, dies or model bases and plaster products used to fix models:

This standard does not apply to dental bone substitutes composed of calcium sulfate hemihydrate (or gypsum):

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document pieces: For undated references, the latest version (including all amendments) applies to this document:

GB/T 131-2006 Product Geometric Technical Specification (GPS) Representation of Surface Structure in Technical Product Documentation (ISO 1302:

2002, IDT)

GB/T 6682-2008 Analytical Laboratory Water Specifications and Test Methods (ISO 3696:1987, MOD) GB/T 7408-2005 Data elements and exchange formats Information exchange date and time representation (ISO 8601:2000, IDT) GB/T 9937.1-2008 Oral vocabulary Part 1: Basic and clinical terms (ISO 1942-1:1989, IDT) GB/T 9937.2-2008 Oral vocabulary Part 2: Oral materials (ISO 1942-2:1989, IDT) GB/T 9937.3-2008 Oral Vocabulary Part 3: Dental Devices (ISO 1942-3:1989, IDT) GB/T 9937.4-2005 Dental Terminology Part 4: Dental Equipment (ISO 1942-4:1989, IDT) GB/T 9937.5-2008 Oral vocabulary Part 5: Terms related to testing (ISO 1942-5:1989, IDT) YY/T 0466.1-2016 Symbols for Medical Device Labeling, Marking and Information Provision for Medical Devices Part 1: General Requirements Seek (ISO 15223-1:2012, IDT)

3 Terms and Definitions

GB/T 9937.1-2008, GB/T 9937.2-2008, GB/T 9937.3-2008, GB/T 9937.4-2005, GB/T 9937.5-2008 and the following terms and definitions apply to this document: