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

YY/T 1027-2018

**Dentistry-Hydrocolloid impression materials
(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 1027-2001 "Dental Alginate Impression Material" and YY 0494-2004 "Dental Agar-Based Hydrocolloid Impression Material":

Compared with YY 1027-2001 and YY 0494-2004, the main technical changes in this standard are as follows except editorial revisions:

- Increased the classification of type 3A agar material, and added the sample preparation steps for type 3A materials to the involved items;
- Added test methods and requirements for tensile bond strength and linear dimensional change of 3A materials;
- Deleted the requirements and test methods for product appearance and blend appearance in YY 1027-2001 and YY 0494-2004, Check this part in Chapter 6 "Test Pretreatment" stage;
- Delete the requirements on the extrusion temperature, gel temperature and extrudability of agar material, and put this part in Chapter 6 "Before the test "Management" stage to check;
- Delete the item of compressive strength of alginate material, and add the item of tear

resistance;

--- Modified the details of the alginate material and agar material reproduction, and the test method was also modified accordingly:

This standard uses the redrafted method to revise and adopt ISO 21563:2013 "Dentistry Hydrocolloid Impression Materials":

The technical differences between this standard and ISO 21563:2013 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:

a) ISO 3696 is replaced by GB/T 6682, which adopts the modified international standard:

b) Replace ISO 1942 (all parts) with GB/T 9937 (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);

c) Replaced ISO 6873 by modifying YY 0462 to adopt the international standard:

Please note that some content of this standard may involve patents: The issuing authority of this standard 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):

1 Scope

This standard specifies the performance requirements and test methods for elastic aqueous agar and alginate hydrocolloid dental impression materials in order to determine their performance Whether to achieve the expected quality of use: It also stipulates the requirements for instructions for use and labels:

This standard applies to elastic aqueous agar and alginate hydrocolloid dental impression materials:

Note: This standard does not contain qualitative and quantitative requirements for possible biological hazards, but it is recommended that when evaluating the possible biological hazards of hydrocolloid impression materials, References ISO 10993 and ISO 7405:

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 6682-2008 Analytical Laboratory Water Specifications and Test Methods (ISO 3696:1987, MOD) 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 0462-2018 Dental plaster products (ISO 6873:2013, MOD)

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:

Adhesive bonding

The viscous properties of the reversible and irreversible impression components in the impression material make each component used alone and needs to cooperate with each other to form A unified impression system to achieve the required degree of flexibility and effective impression and successful removal from the mouth:

bulk container Labeled sales packages or immediate packaging containers containing bulk granules, liquids, powders or other loose substances in quantities usually the amount required for more than one oral clinical treatment or laboratory procedure:

Low-consistency agar material is first injected around the selected tooth, allowing it to communicate with the irreversible alginate impression material when the impression is made:

Impression system for pressure bonding:

sales packaging consumer packaging; retail packaging; sales packaging A sales unit containing the package and its contents that can be offered to the end user or consumer at the time of retail sale:

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