

ICS 11.060.10
CCS C33

YY

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

YY 0714.2-2016

Replacing YY 0714.2-2009

**Dentistry - Soft lining materials for removable dentures - Part 2:
Materials for long-term use**

牙科学 活动义齿软衬材料 第2部分：长期使用材料

Issued on: March 23, 2016

Implemented on: January 1, 2018

Issued by: National Medical Products Administration

Table of Contents

- 1 Scope
- 2 Normative reference documents
- 3 Terms and definitions
- 4 Classification

Foreword

The technical content of this section is mandatory. YY 0714 "dental activity denture soft lining material" consists of two parts. - Part 1. short-term use of materials; - Part 2. Long - term use of materials. This part is part 2 of YY 0714. This part is drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0714.2-2009 "Dental denture soft lining material Part 2. Long term use of materials", and YY 0714.2-2009 compared to the main technical changes are as follows: - the depth of penetration (version

5.1 in 2009) and the corresponding test method (2009 version 6.3); - the depth ratio (2009 edition 5.2) and the corresponding test method (2009 version 6.3) were deleted; - modified the classification (see Chapter 4, Chapter 4 of the 2009 edition); - increased bond strength (see 5.3) and its test methods (see 7.3); - increased water absorption (see 5.4) and its test methods (see 7.4); - increased dissolution values (see 5.5) and their test methods (see 7.4). This part uses the translation method equivalent to ISO 10139-2..2009 "Dental activity denture soft lining material Part 2. Long term use material". In this part of the normative reference to the international documents have a consistent correspondence between the following documents. Test method for press hardness of vulcanized rubber or thermoplastic rubber - Part 1. Shore 's hardness tester GB/T 531.1-2008. (Shore hardness) (ISO 7619-1..2004, IDT); Analysis of laboratory water specifications and test methods (ISO 3696. 1987, MOD); GB/T 6682-2008;

--- GB/T 7408-2005 Data element and exchange format Information exchange date and time representation (ISO 8601..2004, IDT); GB/T 9258.1-2000 Particle size analysis for abrasive abrasives - Part 1. Particle size composition (idt ISO 6344-1. 1998); GB/T 9937 (all parts) Oral vocabulary [ISO 1942 (all parts), IDT]; - YY 0270.1-2011 Dentistry base polymer - Part 1. Denture base polymer (ISO 20795-1..2008, IDT). Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This section is proposed by the State Food and Drug Administration. This part is headed by the National Standardization Technical Committee for Dental Materials and Equipment (SAC/TC99). This part of the drafting unit. the State Food and Drug Administration Peking University Medical Device

Quality Supervision and Inspection Center, Shanghai Second Medical Zhangjiang Biomaterials Material Co., Ltd., Japan into dental materials (Kunshan) Co., Ltd. The main drafters of this part. Lin Hong, Bai Wei, Jiang Lan, Xu Zhenguo, Sun Zhihui, Zheng Rui, Xia Jun, Shen Xiwei. This section was first released in June.2009. YY 0714.2-2016/ISO 10139-2..2009

In this part of YY 0714, the long-term use of oral soft lining materials is classified according to the degree of softness and softness of the material. Though not The evidence shows which soft and hard material is better, but the purpose of this classification is to help the clinician gain more information and make the appropriate s Choice. This part increases the requirements for the bonding strength, water absorption and solubility of the denture base. Using a new test soft lining material soft Hardness test, ie Shore A hardness test. This test replaces the needle penetration test in YY 0714.2-2009. This section does not contain qualitative and quantitative requirements for possible biological hazards, but it is recommended that in assessing possible biological hazards, see YY/T 0268 and GB/T 16886.1. YY 0714.2-2016/ISO 10139-2..2009 Dental activity denture soft lining material Part 2. Long - term use of materials

1 Scope

YY 0714.2 is the mandatory Chinese standard for long-term soft denture lining materials, the resilient layers bonded inside a denture base to cushion it against a ridge that is thin, atrophic or tender. Long-term use is what makes the specification demanding: the material has to stay soft rather than hardening, stay bonded to the denture base rather than peeling, resist colonisation by Candida, and not stain or absorb odour over months of continuous wear in the mouth. The standard sets those requirements and the test methods that verify them. It replaces YY 0714.2-2009 and sits alongside Part 1 for short-term materials. Being a YY standard without the /T suffix, compliance is compulsory in China.

This part of YY 0714 specifies the softness, adhesion, water absorption and solubility of long-term denture soft lining materials, as well as packaging, Logo and manufacturer's instructions. These materials can also be used for maxillofacial repair.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document.

ISO 1942 (all parts) oral vocabulary (Dentistry-Vocabulary)

ISO 3696 Analytical laboratory water specifications and test methods
(Waterforanalyticallaboratoryuse-Specification andtestmethods) ISO 6344-

1 Particle size analysis for abrasive abrasives - Part 1. Coated composition -

Coated abrasives - Grain size analysis-Part 1. Grain size distribution test)

ISO 7619-1 vulcanized rubber or thermoplastic rubber - Test method for hardness - Part 1. Shore 's hardness tester (Shore hardness) [Rubber, vulcanized or thermoplastic-Determination of indentation hardness-Part 1. Durometer method (Shore hardness)]

ISO 8601 data element and exchange format information exchange date and time representation (Data elements and interchange formats-Information exchange-Representation of dates and times) ISO 20795-

1 Dental science base polymer Part 1. Dentistry-Base polymers- Part 1. Denture base polymers)

3 Terms and definitions

ISO 1942 and the following terms and definitions apply to this document.

3.1 Denture soft lining material soft denture lining material Soft and elastic material, adhesion to the denture of the tissue surface, in order to reduce the support of tissue damage.

3.2 Long-term use long-term use Use for more than 28 days.

3.3 Direct packaging container immediate container A container in direct contact with the material.

4 Classification

For the long-term use of the denture soft lining material, according to

7.2 on the 24h Shore A hardness test (5.1) the following classification. YY 0714.2-2016/ISO 10139-2..2009