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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 1042-2023

Dentistry - Polymer-based restorative materials

牙科学 聚合物基修复材料

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1 Scope

YY 1042 is the mandatory Chinese standard for polymer-based restorative materials, the composite resins used to fill and rebuild teeth. Carrying the YY prefix without /T, compliance is compulsory in China rather than advisory. It sets the requirements such a material has to meet and the test methods that verify them, covering the properties that decide clinical performance: how deeply the material cures, how much it shrinks, how it resists wear and fracture, how it holds colour, and what it releases in the mouth. Composite is the most-placed restorative material in dentistry, so this is one of the standards a dental materials company meets first when entering China. The 2023 edition takes effect in December 2026, which is the date a manufacturer has to work back from when planning conformity evidence.

This document specifies the requirements for dental polymer-based restorative materials. This type of material, which is provided in a form suitable for mechanical mixing, manual blending, or intra-oral and extra-oral activation by external energy, is mainly used for direct or indirect restoration and luting of teeth. The polymer-based luting materials covered by this document are intended for use in the cementation or fixation of restorations and restorative devices, such as. inlays, onlays, veneers, crowns and bridges. This document does not cover polymer-based luting materials containing adhesive components (see ISO/TS 16506). This document does not cover dental polymer-based materials used to prevent dental caries (see YY 0622), core materials or veneer materials used on metal bases (see YY 0710).

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 6682-2008 Water for Analytical Laboratory Use - Specification and Test Methods (ISO 3696.1987, MOD)

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

YY/T 0631 Dental Materials - Determination of Color Stability (YY/T 0631-2008, ISO 7491.2000, IDT)

YY/T 1599 Dentistry - Test Method for Polymerization Shrinkage of Polymer-based Restorative Materials - Laser Ranging Method

YY/T 1646-2019 Dentistry - Test Method for Determining Radio-opacity of Materials (ISO 13116.2014, IDT)

ISO 8601-1.2019 Date and Time - Representations for Information Interchange - Part

1.Basic Rules NOTE.

GB/T 7408-2005 Data Elements and Interchange Formats - Information Interchange - Representation of Dates and Times (ISO 8601.2000, IDT)

ISO 8601-2.2019 Date and Time - Representations for Information Interchange - Part 2. Type II. other polymer-based restorative materials and luting materials, except Type I.

4.2 Class Dental polymer-based restorative materials are divided into the following three classes.

---Class I. materials that are cured by mixing initiators and accelerators (self-curing materials).

---Class II. materials that are cured by activation by external energy sources, such as. blue light or heating (see Item 9 and Item 20 in Table 4 for "external energy activated" materials). It can be divided into the following two groups. 1) Group 1.materials that require energy activation in the oral cavity. 2) Group 2.materials that require energy activation outside the oral cavity. After curing is completed, the materials are luted into place. The manufacturer may claim that some materials belong to both Group 1 and Group 2. At this time, this type of material shall simultaneously satisfy the requirements of both groups. NOTE. Class II luting materials only belong to Group 1.

---Class III. materials that are cured by external energy and have a self-curing mechanism (dual curing materials).

5.1 Physical and Chemical Properties

5.1.1 General requirements If the manufacturer provides multiple shades of restorative materials, each shade, including the opaque shade, shall be able to satisfy the various requirements of the materials for ambient light sensitivity (5.1.7) and curing depth (5.1.8), shade (5.2) and color stability (5.3) in the corresponding type and class. If the material provided can be "pigmented" or "mixed" in accordance with the user's requirements, then, the material shall comply with the requirements when used alone and after being tinted or blended with the colorant in the maximum recommended proportion (see Item 19 in Table

4). The curing depth (5.1.8) of the luting materials does not need to be tested. Unless the manufacturer claims that the material has color stability, luting materials do not need to be tested for color stability (5.3). For the other requirements in 5.1, and 5.4, only a representative shade of the restorative materials shall be tested. The representative shade shall be that of a material classified as "universal" by the manufacturer, or, if in the absence of such classification, then, the shade "A3" of Vita1) color classification shall be taken as the representative shade. However, if the manufacturer claims that other colors have higher radio-opacity (see

5.4 and Item 28 in Table 4), then, this claim shall be tested. Performance requirements are summarized in Table 1, Table 2 and Table 3.

5.1.2 Film thickness of luting materials Carry out the test in accordance with 7.5.The film thickness of the luting materials shall not be 10 m greater than the manufacturer's claimed value, and in no case shall the film thickness be greater than 50 m (primary requirement).

5.1.3 Working time of Class I and Class III restorative materials (except luting materials) Carry out the test in accordance with 7.6.The working time of working time of Class I and Class III restorative materials (except luting materials) shall be 90 s.

5.1.4 Working time of Class I and Class III luting materials Carry out the test in accordance with 7.7.The materials shall be able to form a thin layer. During the formation of the thin layer, there shall be no perceptible change in its uniformity.

5.1.5 Curing time of Class I materials When carry out the test in accordance with 7.8, the curing time of Class I restorative materials (except luting materials) shall be 5 min. When carrying out the test in accordance with 7.8, the curing time of Class I luting materials shall be 10 min.

5.1.6 Curing time of Class III materials When carrying out the test in accordance with 7.8, the curing time of Class III materials shall be 10 min.

5.1.7 Ambient light sensitivity of Class II materials When carrying out the test in accordance with 7.9, the materials shall maintain physical uniformity.

5.1.8 Curing depth of Class II materials (except luting materials) First requirement. when carrying out the test in accordance with 7.10, among Class II restorative materials (except luting materials), the curing depth of materials indicated by the manufacturer as shading shall be 1 mm, and the curing depth of other restorative materials shall be

1.5 mm. 1) Vita is a trade name of Vita Zahnfabrik, H Rauter GmbH & CoK G, Postfach 1338, D-79704 Bad Saeckingen, Germany. The information is provided only for the convenience of users of this document and does not constitute a clause of this document. batch number, including the sample required for repeated tests if necessary. The sufficient amount is 50 g.