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

YY/T 1411-2023

Replacing YY/T 1411-2016

**Dentistry - Test methods for dental unit waterline biofilm
treatment**

牙科学 牙科治疗机水路生物膜处理的试验方法

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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 replaces YY/T 1411-2016 "Dentistry measures to improve or maintain the microbiological quality of dental treatment water treatment water Compared with YY/T 1411-2016, except for structural adjustment and editorial changes, the main technical changes are as follows:

- Changed the scope of application (see Chapter 1, Chapter 1 of the:2016 edition);
- Added and changed some terms and definitions (see Chapter 3, Chapter 3 of the:2016 edition);
- Added the preparation method of test water (see 5:1);
- Added "inoculation test water" (see 5:3);
- Increased the provisions of the reconstruction elements of the dental unit waterway system simulation device (see 6:2:1);
- Increased the different effects of antibacterial materials and materials that prevent microbial adhesion on the evaluation test method (see 6:2:2);
- Increase the specific indicators of flow rate, water flow mode, test environment temperature and pre-time (see 6:3);
- Increase the residence time of water for sterility test in the waterway (see 7:2:4);
- Increase the provisions of microbial sampling and testing (see 7:3:2 and 7:3:4);
- Increased sampling requirements (see 8:1:1);
- Changed the method of counting viable bacteria (see 8:1:2 and 8:1:3, 9:2 of the:2016 edition);
- Changed the method of biofilm assessment (see 8:2:2, 9:3 of the:2016 edition);
- Deleted the description of the formation and characteristics of biofilm (see 5:2:2 of the:2016 edition);

1 Scope

YY/T 1411 specifies how to test the treatments used against biofilm in dental unit waterlines. The narrow tubing that feeds a dental handpiece is close to ideal for bacterial growth: warm, low-flow, high surface-to-volume, and idle overnight. The biofilm that forms sheds organisms into water that is sprayed into a patient's mouth, and outbreaks traced to dental waterlines have been documented. This document sets out how a treatment product or protocol is challenged: how a biofilm is established for the test, how the treatment is applied, and how the reduction is measured, so that a manufacturer's claim can be substantiated rather than asserted. The 2023 edition replaces YY/T 1411-2016. For a maker of waterline disinfectants or of dental units, this is the method a Chinese registration expects.

This document provides a method of type testing, mainly used to evaluate the biofilm in the waterway system of the dental unit under laboratory conditions. The effectiveness of treatments to prevent, inhibit their formation or remove: This document does not apply to equipment for conveying sterile treated water or sterile solutions, nor does it apply to equipment for conveying compressed air in dental units. Pipes, pipes or hoses: This document does not set limits on the corresponding microbiological indicators: The method is not applicable in clinical conditions: This document was also not created for Test methods to assess any adverse side effects that may be caused by the treatment: The test methods provided in this document can be used to test other dental devices that deliver non-sterile water to the oral cavity:

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. For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB/T 6682-2008 Analytical Laboratory Water Specifications and Test Methods (ISO 3696:1987, MOD) GB 9706:

1 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance (GB 9706:1-2020, IEC 60601-1:2012, MOD)

GB/T 9937 Terminology in Dentistry (GB/T 9937-2020, ISO 1942-2009, MOD)

GB/T 22592 General Rules for Determination of pH Value of Water Treatment Agents (GB/T 22592-2008, ISO 10523:1994, NEQ) YY/T 1043:

1 Dentistry Dental Units Part 1: General Requirements and Test Methods (YY/T 1043:1-2016, ISO 7494-1:2011, MOD) YY/T 1043:

2 Dentistry Dental Treatment Machine Part 2: Air, Water, Suction and Wastewater Systems (YY/T 1043:2-2018, ISO 7494-2:2015, IDT)

3 Terms and Definitions

The following terms and definitions defined in GB 9706:1, GB/T 9937, YY/T 1043:1 and YY/T 1043:2 apply to this document: 3:

1 Biofilm biofilm A complex of bacterial clumps and extracellular matrix tightly adhered to the surface of an object: 3:

2 Dental treatment machine dentalunit Equipment for dental treatment that is composed of interconnected dental equipment and instruments to form a functional combination:

[Source: GB/T 9937-2020,2:86] YY/T 1141-2023