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Dentistry — Test methods for dental unit waterline biofilm treatment

Médecine bucco-dentaire — Méthodes d'essais pour le traitement du biofilm dans les conduites d'eau de l'unit dentaire

Reference number
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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition of ISO 16954:2015 cancels and replaces the first edition of ISO/TS 11080:2009, of which it constitutes a technical revision.

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Dentistry — Test methods for dental unit waterline biofilm treatment

1 Scope

This International Standard provides type test methods for evaluating the effectiveness of treatment methods intended to prevent or inhibit the formation of biofilm or to remove biofilm present in dental unit procedural water delivery systems under laboratory conditions.

This International Standard does not apply to devices intended to deliver sterile procedural water or sterile solution. It also does not apply to lines, tubing, or hoses that deliver compressed air within the dental unit.

This International Standard does not establish specific upper limits for bacterial contamination or describe test methods to be used in clinical situations. It also does not establish test methods for evaluating any deleterious side effects potentially caused by treatment methods.

The test methods provided in this International Standard can be used to test other dental equipment that delivers non-sterile water to the oral cavity.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7494-1, *Dentistry — Dental units — Part 1: General requirements and test methods*

ISO 7494-2, *Dentistry — Dental units — Part 2: Water and air supply*

ISO 10523, *Water quality — Determination of pH*

ISO 19458, *Water quality — Sampling for microbiological analysis*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, ISO 1942, ISO 7494-1, and ISO 7494-2 and the following apply.

3.1
biofilm
structured community of microorganisms inhabiting a self-developed extracellular biopolymeric matrix attached to a surface

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