SLOVENSKI STANDARD
SIST EN ISO 16954:2015

01-september-2015

Zobozdravstvo - Preskusne metode za ravnanje z vodo v zobozdravstvenih enotah po načinu biofilma (ISO 16954:2015)

Dentistry - Test methods for dental unit waterline biofilm treatment (ISO 16954:2015)

Zahnheilkunde - Prüfverfahren zur Biofilmbehandlung der wasserführenden Leitungen einer dentalen Behandlungseinheit (ISO 16954:2015)

Médecine bucco-dentaire - Méthodes d'essais pour le traitement du biofilm dans les conduites d'eau de l'unit dentaire (ISO 16954:2015)

Ta slovenski standard je istoveten z: **EN ISO 16954:2015**

ICS:

11.060.20	Zobotehnična oprema	Dental equipment

SIST EN ISO 16954:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16954

July 2015

ICS 11.060.20

English Version

Dentistry - Test methods for dental unit waterline biofilm treatment (ISO 16954:2015)

Médecine bucco-dentaire - Méthodes d'essais pour le traitement du biofilm dans les conduites d'eau de l'unit dentaire (ISO 16954:2015)

Zahnheilkunde - Prüfverfahren zur Biofilmbehandlung der wasserführenden Leitungen einer dentalen Behandlungseinheit (ISO 16954:2015)

This European Standard was approved by CEN on 23 April 2015.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 16954:2015) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2016, and conflicting national standards shall be withdrawn at the latest by January 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 16954:2015 has been approved by CEN as EN ISO 16954:2015 without any modification.

INTERNATIONAL STANDARD

ISO 16954

First edition
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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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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