



**NSAI**  
Standards

Irish Standard  
I.S. EN ISO 16954:2015

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

## I.S. EN ISO 16954:2015

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

EN ISO 16954:2015

*Published:*

2015-07-08

*This document was published under the authority of the NSAI and comes into effect on:*

2015-07-25

ICS number:

11.060.20

NOTE: If blank see CEN/CENELEC cover page

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

**EN ISO 16954**

NORME EUROPÉENNE

EUROPÄISCHE NORM

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'unité 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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

**EN ISO 16954:2015 (E)**

**Contents**

**Page**

**European foreword .....3**

## **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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## **Endorsement notice**

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

This page is intentionally left blank

# INTERNATIONAL STANDARD

**ISO  
16954**

First edition  
2015-07-01

---

---

## **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  
ISO 16954:2015(E)

© ISO 2015

**ISO 16954:2015(E)**



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org



# Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Treatment methods</b> .....	<b>3</b>
<b>5 Test water and bacterial challenge suspensions</b> .....	<b>3</b>
5.1 Test water.....	3
5.1.1 Reagents.....	3
5.1.2 Preparation of hardness stock solution 1.....	3
5.1.3 Preparation of hardness stock solution 2.....	3
5.1.4 Preparation of test water prior to inoculation.....	3
5.2 Bacterial challenge.....	4
5.3 Inoculated test water.....	4
<b>6 Test apparatus</b> .....	<b>4</b>
6.1 Test apparatus design.....	5
6.1.1 General.....	5
6.1.2 Considerations specific to antimicrobial materials and materials which prevent microbial adhesion.....	6
6.2 Test apparatus operation.....	6
6.2.1 Flow rates.....	6
6.2.2 Flow patterns (on-off cycles).....	6
6.2.3 Test environment temperature and preconditioning period.....	7
<b>7 Test procedures</b> .....	<b>7</b>
7.1 Testing sequence.....	7
7.2 Biofilm prevention or inhibition.....	7
7.2.1 General.....	7
7.2.2 Pretreatment of the test apparatuses.....	8
7.2.3 Concurrent exposure to inoculated test water and the treatment method for biofilm prevention or inhibition.....	8
7.2.4 Microbiological sampling and testing.....	8
7.2.5 Test duration.....	8
7.2.6 Analysis of results.....	9
7.3 Biofilm removal.....	9
7.3.1 General.....	9
7.3.2 Initial microbiological sampling and testing.....	9
7.3.3 Application of the biofilm removal treatment method.....	10
7.3.4 Final microbiological sampling and testing.....	10
7.3.5 Analysis of results.....	10
<b>8 Microbiological sampling and testing</b> .....	<b>11</b>
8.1 Enumeration of bacteria levels in procedural water.....	11
8.1.1 Sampling.....	11
8.1.2 Total viable count test procedure.....	11
8.1.3 Alternative total viable count test procedure.....	11
8.2 Biofilm on waterline surfaces.....	12
8.2.1 Sampling.....	12
8.2.2 Biofilm assessment test procedure.....	12
<b>9 Test Report</b> .....	<b>13</b>
<b>Bibliography</b> .....	<b>14</b>

## ISO 16954:2015(E)

### 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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
  - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-