

SVENSK STANDARD

SS-EN ISO 15883-4:2019

Fastställt/Approved: 2019-01-02
Utgåva/Edition: 3
Språk/Language: engelska/English
ICS: 11.080.10

Disk- och spoldesinfektorer – Del 4: Krav och provningsmetoder för disk- och spoldesinfektorer med kemisk desinfektion för värmekänsliga endoskop (ISO 15883-4:2018)

Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018)

This preview is downloaded from www.sis.se. Buy the entire standard via <https://www.sis.se/std-80009146>

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka

Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

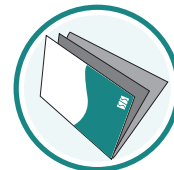
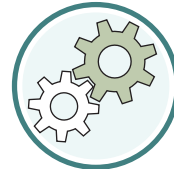
Ta del av det färdiga arbetet

Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standardpaket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete

Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.



Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence

As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

Get to know the finished work

We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception

With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00



Europastandarden EN ISO 15883-4:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 15883-4:2018.

Denna standard ersätter SS-EN ISO 15883-4:2009, utgåva 2

The European Standard EN ISO 15883-4:2018 has the status of a Swedish Standard. This document contains the official version of EN ISO 15883-4:2018.

This standard supersedes the SS-EN ISO 15883-4:2009, edition 2

© Copyright/Upphovsrätten till denna produkt tillhör SIS, Swedish Standards Institute, Stockholm, Sverige. Användningen av denna produkt regleras av slutanvändarlicensen som återfinns i denna produkt, se standardens sista sidor.

© Copyright SIS, Swedish Standards Institute, Stockholm, Sweden. All rights reserved. The use of this product is governed by the end-user licence for this product. You will find the licence in the end of this document.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

EN ISO 15883-4

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2018

ICS 11.080.10

Supersedes EN ISO 15883-4:2009

English Version

Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018)

Laveurs désinfecteurs - Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles (ISO 15883-4:2018)

Reinigungs-Desinfektionsgeräte - Teil 4: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für thermolabile Endoskope (ISO 15883-4:2018)

This European Standard was approved by CEN on 17 August 2018.

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, Serbia, 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

Contents

Page

European foreword	ix
Introduction	xi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Performance requirements	5
4.1 General	5
4.2 Systems for leak testing	7
4.3 Cleaning	9
4.3.1 General.....	9
4.3.2 Flushing.....	9
4.3.3 Washing.....	9
4.3.4 Post-washing rinsing.....	9
4.3.5 Determination of cleaning efficacy.....	10
4.4 Disinfecting.....	10
4.4.1 General.....	10
4.4.2 Efficacy of the disinfectant.....	10
4.4.3 Temperature.....	11
4.4.4 Process monitoring	11
4.4.5 Disinfectant use	11
4.5 Final rinsing	12
4.6 Purging to remove rinse water	12
4.7 Drying.....	13
4.8 Self-disinfection.....	13
4.9 Water treatment equipment.....	14
4.9.1 General.....	14
4.9.2 Disinfection of water treatment equipment.....	14
4.9.3 Maintenance of piping.....	15
5 Mechanical and process requirements	16
5.1 Materials – Design, manufacture and construction	16
5.2 Device channel irrigation system	16
5.2.1 General.....	16
5.2.2 Verification of device channel irrigation by the automatic controller	17
5.3 Venting and drainage systems.....	17
5.4 Temperature control	18
5.4.1 General.....	18
5.4.2 Temperature control of the washing stage	18
5.4.3 Temperature control of the disinfection stage	18
5.4.4 WD with a minimum operating temperature for the washing and/or disinfection stage	18
5.5 Process chemicals.....	18
5.6 Process verification.....	18
5.7 Dosing systems	19
6 Testing for conformity	19
6.1 General	19
6.2 Test equipment.....	19
6.2.1 General.....	19
6.2.2 Pressure measurement.....	19
6.2.3 Flow measurement.....	19
6.3 Water used for final rinsing.....	20
6.3.1 Principle.....	20
6.3.2 Material/procedure	20

6.3.3	Results/acceptance criteria.....	20
6.4	Hardness of water used during type testing.....	20
6.4.1	Principle	20
6.4.2	Material	20
6.4.3	Procedure	21
6.5	Leak test.....	21
6.5.1	Principle	21
6.5.2	Material	21
6.5.3	Procedure	21
6.5.4	Results/acceptance criteria.....	22
6.6	Channels non-obstruction test.....	24
6.6.1	Principle	24
6.6.2	Material	24
6.6.3	Procedure	25
6.6.4	Results/acceptance criteria.....	25
6.7	Channels non-connection test.....	25
6.7.1	Principle	25
6.7.2	Material	26
6.7.3	Procedure	26
6.7.4	Result/acceptance criteria.....	26
6.8	Load dryness.....	26
6.8.1	Principle	26
6.8.2	Material	26
6.8.3	Exterior surface drying.....	26
6.8.4	Channel drying.....	27
6.9	Thermometric tests	27
6.9.1	Test for chamber and load temperature during operating cycle.....	27
6.9.2	Test for operating cycle temperature limits on washing and chemical disinfection stages	28
6.10	Chemical dosing tests for single-dose containers.....	28
6.10.1	Principle	28
6.10.2	Material	28
6.10.3	Procedure	28
6.10.4	Results/acceptance criteria.....	29
6.11	Tests of cleaning efficacy	29
6.11.1	General.....	29
6.11.2	Principle	29
6.11.3	Material	29
6.11.4	Procedure	30
6.11.5	Results/acceptance criteria.....	30
6.12	Tests of disinfection efficacy.....	30
6.12.1	General.....	30
6.12.2	Preliminary tests on chemical disinfectants	31
6.12.3	Self-disinfection tests	33
6.12.4	Test of microbial quality of final rinse water treatment equipment.....	34
6.12.5	Disinfection of liquid transport systems following failure of water treatment equipment	34
6.12.6	Chemical disinfection of the load	35
7	Documentation and inspection	36
8	Information to be supplied by the manufacturer.....	36
9	Marking, labelling and packaging.....	37
10	Information to be requested from the purchaser by the manufacturer.....	37
	Annex A (informative) Summary of activities covered by this document	38
	Annex B (normative) Microbiological testing of the efficacy of chemical disinfection of the load	40

Annex C (normative) Summary of test programmes	44
Annex D (normative) Methods for microbiological evaluation of disinfection of liquid transport system	48
Annex E (normative) Tests for microbial contamination of final rinse water	53
Annex F (informative) Additional notes on microbiological testing of chemical disinfection processes	55
Annex G (informative) Typical specifications of trumpet valves and connection ports	57
Annex H (normative) Establishing endoscope type test groups	63
Annex I (informative) Establishing endoscope product families	76
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	80
Bibliography	82

European foreword

This document (EN ISO 15883-4:2018) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" 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 June 2019, and conflicting national standards shall be withdrawn at the latest by June 2020.

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

This document supersedes EN ISO 15883-4:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative [Annex ZA](#), which is an integral part of this document.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of [Annex ZA](#)', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 14971	EN ISO 14971:2012	ISO 14971:2007
ISO 15883-1	EN ISO 15883-1:2009 + A1:2014	ISO 15883-1:2006 + Amd1:2014
ISO/TS 15883-5	CEN/ISO/TS 15883-5:2005	ISO TS 15883-5:2005

Table — (continued)

IEC 61010-2-040	EN 61010-2-040:2015	IEC 61010-2-040:2015
EN 12353	EN 12353:2013	--
EN 13727	EN 13727:2013+A2:2015	--

Endorsement notice

The text of ISO 15883-4:2018 has been approved by CEN as EN ISO 15883-4:2018 without any modification.

Introduction

This introduction is intended to be read in conjunction with the introduction to ISO 15883-1.

The washer-disinfectors specified in this document are intended to process devices that can be immersed in water or aqueous solutions. For some devices this will require that, prior to processing, relevant parts of the device are protected from immersion in accordance with the device manufacturer's operating instructions.

Fields of application within the scope of the ISO series include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for washer-disinfectors for other applications are specified in other parts of ISO 15883.

Safety requirements for washer-disinfectors are given in IEC 61010-2-040.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector and its intended use, it is noteworthy that:

- a) until verifiable international criteria are adopted, the existing national regulations concerning the use and/or characteristics of the washer-disinfectors remain in force, and
- b) the ISO 15883 series provides no information as to whether the washer-disinfectors can be used without restriction in any of the ISO member states.