BSI Standards Publication

Washer-disinfectors

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 15883-4:2018. It supersedes BS EN ISO 15883-4:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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

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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
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.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's mandate M/023 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	**Clause(s)/sub-clause(s) of this EN**	**Remarks/Notes**
7.3, 1st part only	4.9.2	Covered only in respect of disinfection of the incoming water treatment equipment. Aspects related to manufacturing are not covered
7.6	4.6.2, 4.9.2.3	Standard clause 4.6.2 covers ER 7.6 for the ingress of oil and particles, standard clause 4.9.2.3 for the ingress of microbes into the endoscopes being processed only. Aspects related to manufacturing are not covered.
8.1	4.1.2, 4.1.3, 4.1.5, 4.1.6, 4.1.7, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.2, 5.3, 5.4, 5.5	Covered only in respect of preventing patient and user infection by the effective reprocessing of endoscopes. Aspects related to manufacturing are not covered. The last sentence of ER 8.1 is not covered.

9.1	4.1.2, 4.1.3, 4.1.7, 4.1.8, 4.2.4, 4.8, 4.9, 5.1, 5.2	Covered only in respect of preventing patient cross infection by the effective reprocessing of endoscopes. The last sentence of ER 9.1 is not covered.
13.6 a)	8 k)	Covered for the information required in ER 13.3 j)

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard (according to article 3 of amended Directive 93/42/EEC)

Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.2.1, 2nd dash	4.2.3, 4.2.4, 4.4.4, 4.8.4	Covered in respect of leak detection and process monitoring during endoscope processing and self-disinfection procedure.
1.5.4	4.1.8, 4.2.4 a), 4.2.4 b), 8	Standard clause 4.1.8 and 4.2.4a), 4.2.4 b) cover EHSR 1.5.4 in respect of connections for process chemicals and connection systems between the WD and the endoscope only. Standard clause 8 covers EHSR 1.5.4 second paragraph only.
1.6.5	4.8, 4.9	Standard clause 4.8 covers EHSR 1.6.5 with respect to requiring a self-disinfection cycle, clause 4.9 to requiring a procedure for disinfection of the water treatment equipment to be provided.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Contents

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).

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).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 15883-4:2008), which has been technically revised. The main changes compared to the previous edition are as follows:

— additional annexes for establishing endoscope type test groups and endoscope product families have been included.

A list of all the parts in the ISO 15883 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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.

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Washer-disinfectors —

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

1 Scope

This document specifies the particular requirements, including performance criteria for washer-disinfectors (WD) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

This document also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which can be required to achieve the necessary performance criteria.

The methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring, and requalification of WD periodically and after essential repairs, are also specified.

NOTE 1 In addition, Annex A gives guidance on an appropriate division of responsibility for the range of activities covered by this document.

NOTE 2 WD complying with this document can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended and validated this method of disinfection.

WD complying with the requirements of this document are not intended for cleaning and disinfection of medical devices, including endoscopic accessories, which are heat stable and can be disinfected or sterilized by thermal methods (see ISO 15883-1:2006+Amd 1:2014, 4.1.5).

The specified performance requirements of this document do not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 3 If it is considered that prion protein might be present, particular care is needed in the choice of cleaning agents and disinfectants to ensure that the chemicals used do not react with the prion protein and/or other protein in a manner that can inhibit its removal or inactivation from the load or washer-disinfector.

NOTE 4 This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of the WD, manufacturers of endoscopes, cleaning products, and disinfecting products.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15883-1:2006+Amd 1:2014, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO/TS 15883-5:2005, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*