Irish Standard
I.S. EN ISO 15883-7:2016

Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO 15883-7:2016)

I.S. EN ISO 15883-7:2016

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National Foreword

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15883-7

March 2016

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English Version

Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO 15883-7:2016)

Laveurs désinfecteurs - Partie 7: Exigences et essais pour les laveurs désinfecteurs utilisant la désinfection chimique pour les dispositifs médicaux et les équipements de soins thermosensibles non invasifs et non critiques (ISO 15883-7:2016)

Reinigungs-Desinfektionsgeräte - Teil 7: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für nicht invasive, nicht kritische thermolabile Medizinprodukte und Zubehör im Gesundheitswesen (ISO 15883-7:2016)

This European Standard was approved by CEN on 8 February 2016.

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.

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 15883-7:2016) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers for medical purposes" 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 September 2016, and conflicting national standards shall be withdrawn at the latest by September 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.

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.

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 11737-1	EN ISO 11737-1:2006 + EN ISO 11737-1:2006/AC:2009	ISO 11737-1:2006 + ISO 11737-1:2006/Cor 1:2007
ISO 11737-2	EN ISO 11737-2:2009	ISO 11737-2:2009
ISO 15883-1	EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014	ISO 15883-1:2006 + ISO 15883-1:2006/Amd1:2014
ISO 15883-2	EN ISO 15883-2:2009	ISO 15883-2:2006
ISO 15883-3	EN ISO 15883-3:2009	ISO 15883-3:2006
ISO 15883-4	EN ISO 15883-4:2009	ISO 15883-4:2008
ISO 15883-6	EN ISO 15883-6:2015	ISO 15883-6:2011
ISO/TS 15883-5	CEN ISO/TS 15883-5:2005	ISO/TS 15883-5:2005
IEC 61010–2-040	EN 61010-2-040:2005	IEC 61010-2-040:2005

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INTERNATIONAL STANDARD

ISO 15883-7

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Washer-disinfectors —

Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment

Laveurs désinfecteurs —

Partie 7: Exigences et essais pour les laveurs désinfecteurs utilisant la désinfection chimique pour les dispositifs médicaux et les équipements de soins thermosensibles non invasifs et non critiques

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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).

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 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

ISO 15883-7 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

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

— *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]

— *Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment*

— *Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment*

Introduction

It is intended that this introduction is to be read in conjunction with the introduction to ISO 15883-1.

This part of ISO 15883 is the seventh of a series specifying the performance of washer-disinfectors. It specifies the particular requirements for performance applicable to washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices, and healthcare equipment. Its requirements apply to washer-disinfectors used for cleaning and disinfection of thermolabile equipment for use without further treatment in healthcare settings. Such reusable equipment needs to be cleaned and disinfected, but processing in a washer-disinfector for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3), for endoscopes (see ISO 15883-4), or for non-invasive, non-critical medical devices, and healthcare equipment employing thermal disinfection (see ISO 15883-6) is inappropriate and/or impractical. Examples of such equipment are bedsteads and bedside furniture, trolleys and transport carts, operating tables, footwear, wheelchairs, or aids for the disabled.

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

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

a) until verifiable international criteria are adopted, the existing national regulations concerning the use and/or characteristics of the washer-disinfector remain in force (e.g. the requirement of backflow prevention), and

b) the ISO 15883 series of standards provides no information as to whether the washer-disinfector may be used without restriction in any of the ISO member states.

Washer-disinfectors —

Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment

1 Scope

This part of ISO 15883 specifies the particular requirements for washer-disinfectors (WD) intended to be used for the cleaning and chemical disinfection, in a single operating cycle, of reusable items such as the following:

a) bedframes;

b) bedside tables;

c) transport carts;

d) containers;

e) surgical tables;

f) sterilization containers;

g) surgical clogs;

h) wheelchairs, aids for the disabled.

This part of ISO 15883 also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which may be necessary in order to achieve the required performance.

Devices identified within the scopes of ISO 15883-2, ISO 15883-3, ISO I5883-4, and ISO 15883-6 do not fall within the scope of this part of ISO 15883.

In addition, the methods are specified, as well as instrumentation and instructions required for type testing, works testing, validation (installation, operation, and performance qualification on first installation), routine control, and monitoring, as well as requalifications required to be carried out periodically and after essential repairs.

NOTE WDs corresponding to this part of ISO 15883 can also be used for cleaning and chemical disinfection of other thermolabile and reusable devices as recommended by the device manufacturer.

The performance requirements specified in this part of ISO 15883 may not ensure the inactivation or removal of the causative agent(s) (prion proteins) of Transmissible Spongiform Encephalopathies.

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.