



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 15883-1:2006

ICS 11.080.10

**WASHER-DISINFECTORS - PART 1: GENERAL
REQUIREMENTS, TERMS AND DEFINITIONS
AND TESTS (ISO 15883-1:2006)**

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EUROPEAN STANDARD
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English Version

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)

Laveurs désinfecteurs - Partie 1: Exigences générales, termes et définitions et essais (ISO 15883-1:2006)

Reinigungs-Desinfektionsgeräte - Teil 1: Allgemeine Anforderungen, Definitionen und Prüfungen (ISO 15883-1:2006)

This European Standard was approved by CEN on 16 March 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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



EUROPEAN COMMITTEE FOR STANDARDIZATION
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EN ISO 15883-1:2006 (E)

Foreword

This document (EN ISO 15883-1:2006) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

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of an identical text or by endorsement, at the latest by October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

ANNEX ZA

(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 4, 3, 6, 7.1, 8.1, 9.1, 7.2, 9.2	
5.1	2, 7.3	
5.1.3	4	
5.1.7	7.5	
5.1.8	7.5	
5.2	1, 2, 6, 7.1, 7.2, 7.3, 7.5, 8.1, 9.1, 9.2, 9.3, 12.5, 12.6, 12.7.1, 12.7.2, 12.7.3, 12.7.4, 12.7.5, 13.1	The WD shall comply with the requirements of IEC 61010-2-045
5.4	7.5	Refers only to leakage
5.4.1.2	7.2, 7.5	
5.4.1.3	13.1	
5.4.1.5	1, 2	
5.4.1.6	1, 2	
5.4.1.7	1, 2	
5.4.1.8	1, 2	

EN ISO 15883-1:2006 (E)**Table ZA.1** *(continued)*

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.4.2	13.1	
5.4.3	8.1	
5.4.4	8.1	
5.4.5.2	2	
5.4.5.3	2, 7.5	
5.5.1	2, 7.2	
5.5.2	2	
5.7	3, 7.2, 7.3	
5.8	2, 12.1, 12.7.5	
5.9	3	
5.10.	13.2	
5.11.1	3	
5.11.2	2, 3	
5.11.3	2, 3	The choice of process verification system shall be based on a documented risk analysis
5.11.4	2, 3	
5.12	3, 12.9	
5.13	3	
5.14	3	
5.15	3	
5.16	3	
5.17	3	
5.18	3	
5.19	3	
5.20	12.1	
5.21	12.1	
5.22	2, 3	
5.23	3, 13.1	
5.24	7.2, 7.5	
5.25	7.2, 7.5	
5.27	3	
5.28	3	

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