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Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)

Reinigungs-Desinfektionsgeräte - Teil 2: Anforderungen und Prüfverfahren von Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für chirurgische Instrumente, Anästhesiegeräte, Gefäße, Utensilien, Glasgeräte usw. (ISO 15883-2:2006)

Laveurs désinfecteurs - Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des instruments chirurgicaux, du matériel d'anesthésie, des bacs, plats, récipients, ustensiles, de la verrerie, etc. (ISO 15883-2:2006)

Ta slovenski standard je istoveten z: prEN ISO 15883-2

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

kSIST prEN ISO 15883-2:2009 en

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EUROPÄISCHE NORM

FINAL DRAFT
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English Version

**Washer-disinfectors - Part 2: Requirements and tests for
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Anästhesiegeräte, Gefäße, Utensilien, Glasgeräte usw.
(ISO 15883-2:2006)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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Foreword

The text of ISO 15883-2:2006 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as prEN ISO 15883-2:2009 by Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 15883-2:2006.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

Endorsement notice

The text of ISO 15883-2:2006 has been approved by CEN as a prEN ISO 15883-2:2009 without any modification.

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Annex ZA (informative)

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

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 International Standard | Essential requirements (ERs) of EU Directive 93/42/EEC | Qualifying remarks/Notes |
|---|---|--|
| 4.1.1 | 1, 2, 3, 4, 5, 6, 7.1, 7.2, 7.3, 7.5, 7.6, 8.1, 9.1, 9.2, 9.3, 12.1, 12.5, 12.6, 12.7.1, 12.7.2, 12.7.3, 12.7.5, 13.1, 13.3, 13.4 | The WD shall comply with the requirements of ISO 15883-1:— |
| 4.1.2 | 1, 3, 4, 6, 7.1, 8.1, 9.1 | |
| 4.1.3 | 1, 3, 4, 6, 7.1, 8.1, 9.1 | |
| 4.1.5 | 3, 7.1 | |
| 4.1.6 | 7.3, 8.1 | |
| 4.2 | 3, 8.1 | |
| 4.3 | 3, 8.1 | |
| 4.4 | 3, 8.1 | |
| 5.1 | 3, 8.1 | |
| 5.2 | 3, 8.1 | |
| 5.3 | 3, 8.1 | |
| 6.1 | 1, 2, 3, 4, 7.1, 8.1 | Testing for conformity according to ISO 15883-1:— |
| 6.2 | 3, 8.1 | |
| 6.3 | 3, 8.1 | |
| 7 | 9.1, 13.6 | |
| 8 | 1, 3, 7.1, 7.2, 8.1 | |

| | | |
|-------|--|---|
| | 7.4, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 10.1, 10.2, 10.3, Clause 11, 12.2, 12.3, 12.4, 12.7.4, 12.8, 13.5, 14 | not applicable |
| - | 12.1a) | This relevant Essential Requirement is not addressed in this European Standard |
| 4.1.1 | 13.3 a) | This relevant Essential Requirement is partly addressed in this European Standard |
| - | 13.6 q) | This relevant Essential Requirement is not addressed in this European Standard |

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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prEN ISO 15883-2:2009 (E)

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)

| Clause(s)/sub-clause(s) of this EN | Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC | Qualifying remarks/Notes |
|------------------------------------|--|--|
| 4.1.1 | 1.1.7, 1.2.2, 1.2.3, 1.2.4, 1.2.5, 1.3.2, 1.3.3, 1.3.4, 1.5.1, 1.5.2, 1.5.3, 1.5.5, 1.5.6, 1.5.8, 1.5.13, 1.5.14, 1.6.2, 1.6.3, 1.6.4, 1.6.5 | This relevant EHSR are addressed in this Standard |
| 4.1.1 | 1.1.3, 1.1.5, 1.1.6, 1.2.1, 1.2.6, 1.3.1, 1.3.7, 1.3.8.1, 1.3.8.2, 1.5.4, 1.6.1, 1.7.1, 1.7.2, 1.7.3, 1.7.4 | This relevant EHSR are partly addressed in this Standard |
| | 1.3.9, 1.4.1, 1.4.2, 1.4.3, 1.5.9, 4 | This relevant EHSR are not addressed in this Standard |

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INTERNATIONAL STANDARD

ISO
15883-2

First edition
2006-04-15

Washer-disinfectors —

Part 2:

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

Laveurs désinfecteurs —

*Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la
désinfection thermique des instruments chirurgicaux, du matériel
d'anesthésie, des récipients, des ustensiles et de la verrerie, etc.*



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