DRAFT AMENDMENT ISO 15883-1:2006/DAM 1

ISO/TC **198** Secretariat: **ANSI**

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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

AMENDMENT 1

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

AMENDEMENT 1

ICS 11.080.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the European Committee for Standardization (CEN), and processed under the **CEN-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

Amendment 1 to ISO 15883-1:2006 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, Subcommittee SC , .

Washer-disinfectors —

Part 1:
General requirements, terms and definitions and tests

AMENDMENT 1

Foreword 6th paragraph

Add:

– Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive non-critical medical devices, washbowls, utensils, transit containers etc

Introduction 5th paragraph

Correct reference to 'IEC 61010-2-040'

Page 2 Normative references

Delete the normative reference:

IEC 61010-2-045, *Safety requirements for electrical equipment for mesurment, control and aboratory use – Part 2-045: Particular requirements for wahser-disinfectors used in medical, pharmaceutical, veterinary and laboratory fields*

Add the following normative references:

IEC 61010-2-040*, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

IEC 61326-1, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements*

Page 2 definition 3.4

Revise definition to read “population of viable microorganisms on or in product and/or sterile barrier system“ and add reference: [ISO/TS 11139:2006, definition 2.2].

Page 3 definition 3.5

Correct typographical error in definition and update reference to:

calibration
set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system or values represented by a material measure of a reference material, and the corresponding values realized by standards

[EN 285:2006+A2:2009, definition 3.5]

Page 3 definition 3.14

Add additional term to D value and modify definition to be aligned with ISO/TS 11139:

D_{10} **value**
time or dose required to achieve inactivation of 90% of a population of the test microorganism under stated conditions
[ISO/TS 11139:2006, definition 2.11]

Page 5 definition 3.31

Update publication of reference and add reference definition number: [ISO/TS 11139:2006, definition 2.22]

Page 6 definition 3.41

Update publication of reference and add reference definition number: [ISO/TS 11139:2006, definition 2.27]

Page 6 definition 3.43

Update publication of reference and add reference definition number: [ISO/TS 11139:2006, definition 2.30]

Page 8 definition 3.58

Update publication of reference and add reference definition number: [ISO/TS 11139:2006, definition 2.55]

Page 8 definition 3.65

z **value**
change in exposure temperature of a thermal sterilization process, which corresponds to a tenfold change in *D* value

[ISO 11138-1:2006, definition 3.21]

Page 10, 4.2.1.1

Correct references in second paragraph to [29] to [42] to align with revised bibliography.

Page 14, 5.2

Replace existing text with the following:

5.2.1 The WD shall comply with the requirements of IEC 61010-2-040.

5.2.2 WDs shall comply with IEC 61326-1 regarding electromagnetic compatibility (EMC).

WDs operating in areas intended for medical electrical equipment or in the vicinity of other sensitive equipment shall be regarded as class B equipment as specified by IEC 61326-1.

The immunity performance criteria selected shall ensure that WDs performance as specified by Clause 4 of this standard is met when exposed to disturbance phenomena of IEC 61326-1 Table 2.

5.2.3 Risk analysis shall address the specific WD design and features. Measures taken for risk reduction shall consider aspects such as ease of use, ergonomics and the knowledge, experience and training of the user.

NOTE ISO 14121 or IEC 61508-1 can provide further helpful information.

5.2.4 Risk management for WD design and software shall be performed following the procedures and requirements given in ISO 14937. Specific requirements and acceptance criteria for WD design and software shall be established and documented. The outcome and results shall be documented.

Page 15, 5.3.2.5

Change reference to [23] to align with revised bibliography.

Page 15, 5.4.1.2

Change cross-reference in third paragraph to IEC 61010-2-40.

Page 16, 5.4.1.7

Change cross-reference in third paragraph to IEC 61010-2-40.

Page 16, 5.4.1.9

Change cross-reference in third paragraph to IEC 61010-2-40.

Page 27, 5.20

Add the following text as clause 5.20 i) after 5.20 h):

i) The software shall be validated using state of the art processes and taking into account the principles of development life cycle, risk management, validation and verification.

NOTE The application of standards such as ISO 12100-2: 2003/A1:2009, *Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles,* ISO 13849-2:2003, *Safety of machinery — Safety-related parts of control systems — Part 2: Validation*, and EN 954-1:1997, *Safety of machinery — Safety related parts of control systems — General principles for design* (being replaced by ISO 13849) should be considered.

Page 32, 6.1.3.2

Change reference: (see IEC 61010-2-040)

Page 33, 6.1.6

Add the following note to the first paragraph:

NOTE If necessary, the responsible person can approve temporary use of the WD pending approval of this documentation by the designated person.

Page 34, 6.2.2.2

Add the following note:

NOTE It might be appropriate to use thermometric recording equipment with fewer than twelve sensors for PQ studies (see Table A.1).

Page 47, 6.10.2.1

Change references to [29] to [42] to align with revised bibliography.

Page 53, 8.3

Add the following text as clauses 8.3 j) and 8.3 k) after clause 8.3 i):

j) the instructions for use must contain their date of issue and their revision number;

k) the name and address of the manufacturer, or, if the manufacturer does not have a registered place of business in the country or the economic area (e.g. European Union) into which the washer-disinfector is being sold and/or installed, the name and address of a representative authorized to act on their behalf.

Page 53, 9.1

Change reference: IEC 61010-2-040

Page 63, C.1.1

Change references to[24] and [39] to align with revised bibliography.

Page 64, C.2.1

Change references to [25] and [26] to align with revised bibliography.

Page 65, C.3.1

Change references to [27] and [28]) to align with revised bibliography.

Pages 69 to 70, Bibliography

Replace the entire bibliography with the following revision to align with cross-references in the text:

[1] ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

[2] ISO 9001, *Quality management systems — Requirements*

[3] ISO 10993 (all parts), *Biological evaluation of medical devices*

[4] ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

[5] ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

[6] ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the validation of a sterilization process*

[7] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[8] ISO 14121-1:2007, *Safety of machinery — Risk assessment — Part 1: Principles*

[9] ISO 14698-1, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods*

[10] ISO 15883-2, *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

[11] ISO 15883-3, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

[12] ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

[13] ISO 17665-1, Sterilization *of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

[14] ISO/TS 11139, *Sterilization of health care products — Vocabulary*

[15] IEC 60073, *Basic and safety principles for man-machine interface, marking and identification — Coding principles for indicators and actuators*

[16] IEC 61508-1:2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems—— Part 1: General requirements*

[17] EN 285:2006+A2:2009, *Sterilization — Steam sterilizers — Large sterilizers*

[18] EN 1717, *Protection against pollution of potable water in water installations and general requirements of devices to prevent pollution by backflow*

[19] EN 1822-1:1998, *High efficiency air filters (HEPA and ULPA) — Part 1: Classification, performance testing, marking*

[20] 80/778/EEC, *Council Directive of 15 July 1980 relating to the quality of water intended for human consumption*

[21] 97/23/EEC, *Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment*

[22] 93/42/EEC, *Council Directive of 14 June 1993 concerning medical devices*

[23] WHO – *Guidelines for drinking-water quality 1996*

[24] DE BRUIJN, A.C.P., ORZECHOWSKI, T.J.H., WASSENAAR, C. Validation on the Ninhydrin Swab Test to monitor cleaning of medical instruments. *Zentr. Steril.* **9**, 2001, pp. 242-247

[25] MICHELS, W., FRISTER, H., PAHLKE, H., FERY, R. Testing the cleaning performance of automated decontamination processes for minimally invasive instruments. *Hyg. Med*. **21**, 1996, pp. 324-330

[26] FRISTER, H., MEISEL, H., SCHLIMME, E. OPA-method modified by use of *N,N*-dimethyl-2-mercaptoethylammonium-chloride as thiol compound. *Fresenius Z Anal Chem*. **330**, 1988, pp 631-633

[27] SMITH, P. K. *et al*. Measurement of Protein Using Bicinchoninic Acid. *Analytical Biochemistry* **150**, 1985, pp. 76-85

[28] MATSUSHITA, M., IRINO, T., COMODA, T., SAKAGISHI, Y. Determination of proteins by a reverse biuret method combined with the copper-bathocuproine chelate reaction. *Clinica Chimica Acta* , **216**, 1993, pp. 103-111

[29] SIS - TR 3:2002, *Washer-disinfectors — Test for cleaning efficacy*

[30] ORZECHOWSKI, T.J.H., and de BRUIN, A.C.P. *Test soil for use on stainless steel items including surgical instruments*. RIVM Bilthoven

[31] ORZECHOWSKI, T.J.H., DE BRUIN, A.C.P., WASSENAAR, C. *Validation of a cleaning test for flexible endoscopes*. CENTRAL SERVICE Vol. 11, 2003

[32] *Richtlinie des Bundesgesundheitsamtes zur Prüfung von thermischen Desinfektionsverfahren in Reinigungsautomaten. Bundesgesundheitsblatt*, **23**, 1980, pp. 364-367

[33] *Qualitätssicherung von Reinigungs- und Desinfektionsprozessen, Anforderungen, Prüfmethoden, Dokumentation, Bezugsquellen, Herausgeberinnen.* C. Höller, S. Krüger, H. Martiny und R. Zschaler, Behr's Verlag Hamburg, 2003

[34] *Überprüfung von Reinigungs-Desinfektionsautomaten im praktischen Betrieb*. Behr's Verlag, Hamburg 1994

[35] DIN 58955-3, *Dekontaminationsanlagen im Bereich der Medizin — Teil 3: Prüfung auf Wirksamkeit*.

[36] DIN 10510, *Lebensmittelhygiene- Gewerbliches Geschirrspülen mit Mehrtank-Transportgeschirrspülmaschinen — Hygienische Anforderungen, Verfahrensprüfung*

[37] Prüfung und Bewertung der Reinigungs und Desinfektionswirkung von Endoskop-Dekontaminations- sowie Desinfektionsautomaten. *Hygiene und Medizin*, **20**, 1995, pp. 40-47

[38] Testing and evaluating the cleaning and disinfection efficacy of washer-disinfectors and disinfection automats. *Hyg. Med*., **20,** 1995, pp. 40-47, *Hygiene und Medizin*, 26, 2001, p. 524

[39] Health Technical Memorandum 2030. *Washer-disinfectors — Validation and verification*. The Stationery Office, London. 1997, ISBN 0-11-322071-5

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[41] KOLLER, W. *Cleaning and Disinfection of crockery and cutlery, instruments and containers for excreta in hospitals*. Verlag Göschl. Wien, 1981

[42] ASTM E2314:03, *Standard test method for determination of effectiveness of cleaning processes for reusable medical instruments using a microbiologic method (simulated use test).* Philadelphia: ASTM International, 2008