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AMENDMENT 1
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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

Reference number
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Foreword

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The committee responsible for this document is ISO/TC 198, *Sterilization of health care products* in collaboration with European Committee for Standardization (CEN) Technical Committee TC 102, *Sterilizers for medical purposes*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Washer-disinfectors —

Part 1:
General requirements, terms and definitions and tests

AMENDMENT 1

Page v, Foreword

Add the following part to the list of parts:

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

Page vi, Introduction

Delete the fifth paragraph: "Safety requirements for washer-disinfectors are given in IEC 61010-2-045.".

Page 2, Normative references

Delete the reference to IEC 61010-2-045.

Add the following references:

IEC 61010-2-040:2005, *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 61326-1:2006, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements*

Page 2, 3.4

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

Page 3, 3.5

Correct the typographical error in the definition of calibration, and update the reference as follows:

> 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 or a reference material, and the corresponding values realized by standards
>
> [SOURCE: EN 285:2006+A2:2009, 3.5]

Page 3, 3.14

Add the admitted (additional) term "D_{10} value" following "*D* value", and modify the definition so as to align it with ISO/TS 11139 as follows:

***D* value**

D_{10} value

time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions

[SOURCE: ISO/TS 11139:2006, 2.11]

Page 5, 3.31

Update reference publication date and add reference definition number: "[SOURCE: ISO/TS 11139:2006, 2.22]".

Page 6, 3.41

Update reference publication date and add reference definition number: "[SOURCE: ISO/TS 11139:2006, 2.27]".

Page 6, 3.43

Update reference publication date and add reference definition number: "[SOURCE: ISO/TS 11139:2006, 2.30]".

Page 8, 3.58

Update reference publication date and add reference definition number: "[SOURCE: ISO/TS 11139:2006, 2.55]".

Page 8, 3.65

In the definition of *z* value, replace the definition by "temperature change required to effect a ten fold change in *D* value".

Add reference definition number: "[SOURCE: ISO 17665-1:2006, 3.61]".

Page 10, 4.2.1.1

Replace the references in the second paragraph with "References [13], [14], [15], [22], [23], [24], [25], [35] to [44]" to align with the revised Bibliography.

Page 14, 5.2

Replace the existing text with the following:

5.2.1 The WD shall comply with the requirements of Clauses 4 to 16 of IEC 61010-2-040:2005.

NOTE Compliance with IEC 61010–2-040:2005 does not meet all safety aspects.

5.2.2 WDs shall comply with IEC 61326-1:2006 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 61326-1:2006.

The immunity performance criteria selected shall ensure that WD performance as specified by Clause 4 (of this part of this International Standard) is met when exposed to disturbance phenomena of IEC 61326-1:2006, 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 12100[8] or IEC 61508–1[18] 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 14971[12]. 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

Replace "(see Reference to [18])" with "(see Reference to [29])" to align with revised Bibliography.

Page 15, 5.4.1.2

Replace the cross-reference in the third paragraph with "IEC 61010-2-040:2005, Clause 15".

Page 16, 5.4.1.7

Replace the cross-reference in the third paragraph with "IEC 61010-2-040:2005, 7.101 and 7.102".

Page 16, 5.4.1.9

Replace the cross-reference in the third paragraph with "IEC 61010-2-040:2005, 7.1.101, 7.101, 7.102, 7.106 and 13.1.103".

Page 27, 5.20

Add 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 ISO 12100[8] and ISO 13849–2[10] can support activities to be performed.

Page 28, 5.24.1

Replace the cross-reference in the fourth paragraph with "IEC 61010-2-040:2005, 11.7.4".

Page 32, 6.1.3.2

Replace the cross-reference in the first paragraph with "(see IEC 61010-2-040:2005, 5.4.3)".

Page 34, 6.2.2.2

Replace the first sentence with: "The thermometric recording instrument(s) shall record the temperature from the minimum number of temperature sensors at locations as specified in 6.8.".

Page 47, 6.10.2.1

Replace the reference numbers with: "References [13], [14], [15], [22], [23], [24], [25], [35] to [44]" to align with the revised Bibliography.

Page 51, 8.2 e)

Replace the cross-reference with "IEC 61010-2-040:2005, Clause 12".

Page 53, 8.3

Add 8.3 j) and 8.3 k) following 8.3 i):

j) the instructions for use shall 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) in which the WD is being sold and/or installed, the name and address of a representative authorized to act on their behalf.

Page 53, 9.1

In the first sentence, replace the reference with: “IEC 61010-2-040:2005, Clause 5”.

Replace b) and c) with the following:

b) the lowest and highest pressure of water and steam (total pressure) provided to the WD;

c) the lowest and highest water temperature (for each type of water) provided to the WD.

Page 63, C.1.1

Replace the reference numbers with:”[30] and [42]” to align with revised Bibliography.

Page 64, C.2.1

Replace the reference numbers with:”[31] and [32]” to align with revised Bibliography.

Page 65, C.3.1

Replace the reference numbers with:”[33] and [34]” to align with revised Bibliography.

Pages 69 to 70, Bibliography

Replace the entire Bibliography with the following.

[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/TS 11139:2006, *Sterilization of health care products — Vocabulary*

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

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

[8] ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

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

[10] ISO 13849-2:2012, *Safety of machinery — Safety-related parts of control systems — Part 2 Validation*

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

[12] ISO 14971 *Medical devices — Application of risk management to medical devices*

[13] 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.*

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

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

[16] 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*

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

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

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

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

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

[22] ASTM E2314:03, *Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)*

[23] DIN 58955-3, *Decontamination equipment for medical use — Part 3: Efficiency testing*

[24] DIN 10510, *Food hygiene — Commercial dishwashing with multitank-transportdishwashers — Hygiene requirements, procedure testing*

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

[26] 98/83/EC, *Council Directive of 3 November 1998 on the quality of water intended for human consumption*

[27] 97/23/EEC, *Directive 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*

[28] 93/42/EEC, *Council Directive of 14 June 1993 concerning medical devices*

[29] *Guidelines for drinking-water quality.* WHO, *1996*

[30] De Bruijn, A.C.P., Orzechowski, T.J.H., Wassenaar, C. Validation of the Ninhydrin Swab Test to monitor cleaning of medical instruments. *Zentr. Steril.* **9**, 2001, pp. 242-247

[31] 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

[32] 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

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

[34] 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

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

[36] Orzechowski, T.J.H., de Bruijn, A.C.P., Wassenaar, C. *Validation of a cleaning test for flexible endoscopes*. CENTRAL SERVICE Vol. 11, 2003

