



BSI Standards Publication

Washer-disinfectors

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

National foreword

This British Standard is the UK implementation of EN ISO 15883-7:2016.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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 (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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by September 2016.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

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15883-7:2016 has been approved by CEN as EN ISO 15883-7:2016 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European standards to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of EU Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
7.2	9	In addition requirements of EN ISO 15883-1 apply. Reference to IEC 61010-2-040:2005, Clause 5 included in respect of packaging only
7.3	4.1.1, 4.1.4	
7.4		WD is not designed to deal with such medical products
7.5	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.24.1

Essential Requirements of EU Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
7.6	4.1.1, 4.7.1	
8.1	4.1.1, 4.3, 4.5, 4.7.2	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 4.3.1
9.1	4.1.1, 4.1.3, 5.1.1, 8 a)	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.9, 5.1.10, 5.6 and 5.28
9.2	4.1.1, 4.1.3, 5.1.1, 5.1.2	Including reference to IEC 61010-2-040:2005, 5.4.3 and 7.5
9.3		WDs are unlikely to be manufactured of or to contain flammable or explosive substances
10.1		Not likely to apply, see MEDDEV 2.1
11		Intended hazardous radiation is unlikely to be emitted by a WD
12.1	4.1.1	
12.5	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.2
12.6	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.1	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.2	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.3	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
12.7.5	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1

Essential Requirements of EU Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
12.9	4.1.1	
13.1	4.1.1	
13.2	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.10.3
13.3 a), b), d)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 9.1
13.3 i)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.29
13.3 k)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.3
13.3 l)	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 9.1
13.4	4.1.1	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 8.1 b)
13.6 a)		Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 9.1
13.6 b)	8 f)	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 8.3
13.6 c)	4.1.4, 4.3.4	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 8.2 h)
13.6 d)	8 a), c), h)	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 6.1.3.2, 8.1 and 8.3 g)
13.6 q)	8	Including reference to EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, Clause 8

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)

Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.3 and 5.2.4
1.1.2	4.1.1, 5.1.1, 5.1.2	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1
1.1.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.1, 5.1.2, 5.2 and 5.3.2 a)
1.1.5	4.1.1	See in addition EN ISO 15883-1:2009, 9.2
1.1.6	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.12.3, 5.27.1 and 6.6.2
1.1.7	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2
1.2.1, 1st dash and 2nd dash	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.2, 5.2.4, 5.12.1, 5.20 and 5.22
1.2.2, 1st dash	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2, 5.12.3, 5.12.8 and 5.12.9
1.2.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.2.4.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 5.19

Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
1.2.5	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.18 and 5.19
1.2.6	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2 and 5.4.1.9
1.3.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 Including reference to EN 61010-2-040:2005, 7.3
1.3.2	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1, 5.2.1 and 8.3 g)
1.3.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.3.4	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.6 and 5.2.1 Including reference to EN 61010-2-040:2005, Clause 7
1.3.7	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.3.8	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.3.9	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.2	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1

Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
1.5.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.4	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 8.3
1.5.5	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.6	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 5.8
1.5.7	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.8	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.9	4.1.1	See in addition EN ISO 15883-1:2009, 5.2.1
1.5.13	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 8.1 b) Including reference to EN 61010-2-040:2005, Clause 11
1.5.14	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 Including reference to EN 61010-2-040:2005, Clause 15
1.5.15	4.1.1, 5.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1
1.5.16	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1

Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
1.6.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.5 and 5.2.1
1.6.2	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.1.5 and 5.2.1
1.6.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 8.2 a) and b)
1.6.4	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 5.4.1.6
1.6.5	4.1.1, 4.5	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 4.2.1.1 and 5.1.10
1.7.1	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1, 5.10.2, 5.10.3 and 5.20 h)
1.7.2	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 8 f)
1.7.3	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, 5.2.1 and 9.1
1.7.4	4.1.1	See in addition EN ISO 15883-1:2009 + EN ISO 15883-1:2009/A1:2014, Clause 7 and Clause 8

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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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-disinfectors 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 15883-4, 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.

ISO 15883-1:2006+A1:2014, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

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

ISO 15883-6, *Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment*

ISO/TS 15883-5:2005, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

EN 10088-2, *Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1, ISO 15883-4, and ISO 15883-6 apply.

4 Performance requirements

4.1 General

4.1.1 The WD shall conform to ISO 15883-1:2006+A1:2014 except for the following subclauses:

- 4.3.1 (which refers to thermal disinfection);
- 5.9 [process temperature control limits, excluding 5.9 d) and e)];
- 5.11 (process verification).

4.1.2 The WD shall be designed to clean and chemically disinfect the range of reusable items specified.

4.1.3 When necessary, the WD shall be provided with means to facilitate the correct alignment of the load in the washing chamber.

4.1.4 The means to control the volume of the process chemical(s) admitted (see ISO 15883-1:2006+A1:2014, 5.7.4 and 5.7.5) shall be adjustable by means of a key, code, or tool. The accuracy of the dosing system shall be at least $\pm 10\%$ or as specified and tested for conformity (see [6.6](#)).

4.1.5 The automatic controller shall ensure that the final concentration of disinfectants are within the limits specified.

NOTE Confirmation of the concentration of disinfectant can include the measurement of the volume of disinfectant and water admitted together with a certificate of conformity from the disinfectant supplier for the concentration of the disinfectant, together with data to support the shelf life, expiry date, etc.

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1 using the test soils and methods described in ISO/TS 15883-5 that are relevant to the loads to be processed.

4.2.2 During the washing stage:

- a) the washing stage starts when the temperature at the control sensor of the WD is not less than the specified washing temperature;
- b) the washing temperature band shall have the lower limit defined by the washing temperature and an upper limit of not greater than the specified washing temperature +10 °C (see ISO 15883-1:2006+A1:2014, 4.2.3).

4.2.3 Cleaning efficacy shall be determined in accordance with [6.7](#).

4.2.4 If the WD is designed to allow the reuse of the cleaning solution on two or more consecutive operating cycles, then care shall be taken to ensure that the efficacy and safety (e.g. accumulation of foreign material, device compatibility) of the cleaning solution is not impaired. This shall include at least the following:

- a) specified methods which shall be used to ensure that the cleaning solution has retained the required cleaning efficacy. These methods shall be based on validation studies, which would normally be carried out by the cleaning solution manufacturer, to determine a suitable parameter, parameters and/or indicators/markers that may be monitored. Suitable parameters may include the concentration of the active ingredient and other ingredients that may also affect performance (e.g. pH);

NOTE Minor changes in formulation of the cleaning solution can have a significant effect on its stability, cleaning efficacy, etc.

- b) recommendations to the user for the maximum period or number of operating cycles for which the cleaning solution may be used. This shall be based on validated experimental data;
- c) where validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall
 - operate an audible and visible alarm and prevent the use of the operating cycle until the cleaning solution is changed, or
 - effect an automatic change of the cleaning solution in the WD.

4.3 Disinfection

4.3.1 The cycle shall include a chemical disinfection stage, which may be combined with the cleaning and shall be deemed to have been achieved when testing requirements in [6.8](#) are met.

4.3.2 The requirements and tests in this part of ISO 15883 are based on the use of aqueous disinfectant solutions. Other systems based on gaseous disinfectants are not excluded; equivalent tests are required. These shall include the following:

- a) disinfectant(s) to be used, for which *in vitro* efficacy has been demonstrated based on relevant published standards;

For the purpose of efficacy testing, a validated neutralization method shall be used. This method can be provided by the disinfectant manufacturer.

- b) when tested on surfaces for the minimum exposure time at the minimum concentration and the minimum temperature to be used in the WD, the disinfectant demonstrates the following:
 - 1) at least a 5 log₁₀ inactivation of vegetative bacteria;
 - 2) at least a 4 log₁₀ inactivation of yeast-like fungi;
 - 3) at least a 4 log₁₀ inactivation of enveloped viruses.

NOTE 2 National Regulatory Authorities can require higher inactivation values and/or efficacy against a wider range of microorganisms.

NOTE 3 Efficacy tests against vegetative bacteria can exclude mycobacteria. See also 8 f).

- c) the compatibility of the cleaning and disinfection solutions are indicated, including any impact on disinfection efficacy from carryover of cleaning solution;
- d) the experimental conditions of tests intended to demonstrate the microbicidal efficacy of the disinfectant *in vitro* shall reflect the conditions of use of the disinfectant. Thus, when cleaning and disinfection is combined, the disinfectant shall be tested in the presence of applicable interfering substances that shall include soiling typically found in the loads to be processed.

4.3.3 The temperature of the disinfectant solution throughout the disinfection stage shall be monitored to ensure that it remains within the specified limits of the disinfectant and be compatible with the temperature limits for the device(s) to be processed.

This shall be achieved either by controlling the temperature of the disinfectant solution or where the temperature in the WD is not controlled that the operation of the WD is prevented outside the specified disinfectant temperature range.

4.3.4 If the WD is designed to allow the reuse of the disinfectant solution on two or more consecutive operating cycles, then care shall be taken to ensure that the efficacy and safety (e.g. accumulation of foreign material, device compatibility) of the disinfectant solution is not impaired. This shall include at least the following:

- a) the means which shall be used to ensure that the disinfectant solution has retained the required antimicrobial disinfection efficacy. These means shall be based on validation studies, which would normally be carried out by the disinfectant manufacturer, to determine a suitable parameter, or parameters and/or indicators/markers that may be monitored to indicate the antimicrobial efficacy of the disinfectant. Suitable parameters may include the concentration of the active ingredient and other ingredients that may also affect performance (e.g. pH, stability, etc.);

NOTE 1 Minor changes in formulation of the disinfectant can have a significant effect on storage life, antimicrobial efficacy, etc.

- b) recommendations to the user for the maximum period or number of operating cycles for which the disinfectant may be used. This shall be based on validated experimental data;
- c) when validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall provide an audible and/or visible indication and prevent the use of the operating cycle until the disinfectant solution is changed (manually or automatically);
- d) provide a method for the user to monitor the disinfectant using a chemical indicator or other method specific for the disinfectant to show that the disinfectant is at or above the minimum recommended concentration.

NOTE 2 The minimum recommended concentration is the lowest concentration of active and other ingredients to meet the label claim of a reusable disinfectant.

4.4 Final rinsing

The water quality used for rinsing after the disinfection stage shall not impair the result of cleaning/disinfection when tested in accordance with [6.3](#).

NOTE WHO definition for potable water or National Regulatory Authorities can be considered.

4.5 Self-disinfection

4.5.1 A self-disinfection cycle shall be provided to ensure that the WD does not become a focus for contamination of the load and to provide a means of disinfecting the WD after interventions for maintenance, repairs, or testing (see also ISO 15883-1:2006+A1:2014, 5.3.1.2).

NOTE 1 The self-disinfection process is intended also to deal with the situation where the WD has become contaminated. Biofilm can easily develop in the piping used to convey rinse water to the load and can contain microorganisms in a state in which they are highly resistant to disinfection.

Thermal disinfection shall attain a minimum A_0 of 60 and shall be capable to be set to give an A_0 -value of 600.

If the use of thermal disinfection is not possible, a chemical disinfectant different from that used for disinfecting the loads shall be used.

NOTE 2 The use of a disinfectant based on the same active ingredients can carry the risk of allowing organisms resistant to a particular disinfectant to proliferate.

4.5.2 Details of the parts of the WD subjected to the self-disinfection cycle shall be provided and whether this cycle includes other components such as the water treatment equipment.

4.5.3 The WD self-disinfection cycle shall

- a) be operated under the control of the automatic controller,
- b) be a user selectable cycle,
- c) provide for disinfection of the chamber and all liquid transport systems,
- d) include means to warn the user that the WD shall be operated without any load in the chamber and, so far as may be practicable, include means to verify that no device is present before the cycle will operate, and
- e) in the case of thermal self-disinfection of the WD, ensure that all the parts of the heating system and the associated pipework, via which the water or the steam reach the WD tank, attain an A_0 -value of at least 60.

4.5.4 The self-disinfection cycle shall ensure that contamination through failure of the water treatment equipment can be effectively disinfected. Compliance shall be verified by testing in accordance with [6.8.3](#).

4.5.5 Thermal disinfection systems shall be evaluated by thermometric monitoring of the system with sensors placed at those parts of the system specified as representative of the lowest temperatures in the system. The entire system subjected to thermal disinfection shall attain the required disinfection temperature.

4.5.6 For chemical self-disinfection cycles, a microbiological test shall be required. The capability of the WD to provide self-disinfection shall be deemed to have been established when tested in accordance with Annex B.

4.6 Drying

4.6.1 The WD shall, unless otherwise specified, be provided with equipment to allow drying of the load.

4.6.2 Drying of the load in the WD shall be deemed to have been achieved when plain surfaces of the items are visibly dry (see [6.4](#)).

4.7 Water treatment equipment

4.7.1 General

Means shall be provided to ensure any water treatment equipment that is part of the WD (softeners, de-ionizers, filters, etc.) is operated within the limits (e.g. flow rates, supply pressures) specified for the water treatment equipment.

4.7.2 Disinfection of water treatment equipment

4.7.2.1 When the water treatment equipment is a part of the WD, the former shall be designed and constructed to allow for periodic disinfection. Guidance on the minimum frequency that the equipment is disinfected shall be provided in accordance with the information supplied by the purchaser for the quality of the water supply and the water treatment equipment [see [8 c](#)) and h)].

NOTE The disinfection of the water treatment equipment can be carried out during a self-disinfection cycle.

The actual frequency should be decided by the user based upon known, e.g. seasonal, variations in the quality of water supplied to the WD and the operational history of the water treatment equipment.

The disinfection method shall not cause any damage to, nor impair the efficacy of, the treatment equipment.

The efficacy of the water equipment disinfection procedure to provide self-disinfection shall be deemed to have been established if, when tested in accordance with [6.3](#), there shall be less than 10 CFU recovered from each of two 100 ml samples and that other control parameters (e.g. temperature, holding time) have been achieved.

4.7.2.2 If the water treatment equipment is not part of the WD, the requirements for water supplied to the WD shall be specified. This shall include specification of the permissible microbial contamination of the water supply [see [8 i](#))].

NOTE 1 To meet the specification of the permissible microbial contamination of the water supply, it can be necessary for the user to make provision for disinfection of the external water treatment equipment.

Final rinse water shall have less than 10 CFU/100 ml sample (see [6.3](#)). If required, means shall be provided to disinfect water used for the final rinse.

NOTE 2 The following methods can be suitable for control of the microbial contamination of rinse water:

- maintained in a dedicated reservoir at a temperature not less than 65 °C for the time demonstrated to achieve disinfection of the incoming supply;
- disinfected immediately prior to use;
- filtered to remove suspended particles of a size greater than 0,2 µm;
- sterile, in a closed container, with a connection to the WD designed and constructed to provide aseptic transfer.

4.7.2.3 The connection between the water supply, which has been treated to remove microbial contamination and the circulation system for rinsing, shall be designed and constructed to provide aseptic transfer.

Provision shall be made for disinfection of this connection to be made periodically. The frequency and method of carrying out this disinfection shall be specified.

4.7.2.4 When the water treatment equipment is a part of the WD, from the time before the rinsing stage until the end of the processing cycle, as appropriate, the final water treatment used to fulfil the requirements of 4.4 shall be monitored by the WD automatic controller to verify that the parameters affecting the efficacy of the water treatment equipment remain within specification.

4.7.3 Maintenance of piping

The planned preventive maintenance required for the piping that is part of the WD and is used to convey final rinse water to the load shall be specified.

5 Mechanical requirements

5.1 Materials — Design, manufacture, and assembly

5.1.1 The WD should be constructed so that loading and unloading of medical equipment are possible without the need to enter the chamber.

5.1.2 The WD design should consider the ease of access for maintenance (IEC 61010-2-040:2005, 5.4.3 and 7.5).

5.2 Process verification

The WDs shall be equipped with a level b process verification system (see ISO 15883-1:2006+A1:2014, 5.11.4).

6 Testing for conformity

6.1 General

The tests described in this subclause are in addition to the tests described in ISO 15883-1 and are specific for WDs intended to process non-invasive, non-critical thermolabile medical devices, and healthcare equipment. They are reference tests intended for use in demonstrating compliance with the specified requirements of this part of ISO 15883. They may be used in type tests, works tests, and in validation and re-qualification tests, or in routine tests carried out by, or on behalf of, the user. Other tests and methods providing equivalent assurance may be used as the basis of claiming compliance with this part of ISO 15883. In any case of dispute, the reference tests given in this part of ISO 15883 shall be used.

The summary programme of tests in addition to those given in ISO 15883-1 is shown in Annex A.

NOTE A number of the tests can be carried out simultaneously with each other and/or with those required by applicable safety standards such as IEC 61010-2-040.

6.2 Test load

6.2.1 Loading with standard goods

Test load shall be defined to represent typical loading of goods to be processed such as bedsteads and bedside tables.

6.2.2 Loading with special goods

If non-critical, non-invasive medical devices that were not included in the type test are to be processed, then a performance qualification shall be carried out with representative loads.

6.3 Water used for rinsing following disinfection

Water used for final rinsing shall be collected from within the WD chamber and tested for microbial quality in accordance with Annex C.

Where the final rinse water is collected after contact with the load, a neutralisation method shall be used to eliminate any antimicrobial activity.

The test shall be carried out following installation. Testing shall be repeated weekly until it has been established that the final rinse water is consistently within specification for at least one month. Testing shall then be repeated annually thereafter.

NOTE Tests for other microorganisms that can be of clinical significance (e.g. *Acinetobacter*) can be performed.

6.4 Load dryness

6.4.1 General

When the WD is intended to dry the load, testing shall be carried out as described below.

6.4.2 Procedure

The WD will be loaded in accordance with manufacturer's instructions (see [6.2](#)) and run through a complete cycle including the drying stage. After completion of the cycle, the door (unloading) is opened and remains open for 5 min before the load is removed from the chamber. The load dryness is inspected visually.

6.4.3 Results

Report whether or not plain surfaces of the load are free visible water.

6.5 Thermometric tests

6.5.1 General

The tests shall be performed in accordance with ISO 15883-1:2006+A1:2014, 6.8.

6.5.2 Load temperature test

The load temperature test shall be carried out using reference loads made up of a full load of items that the WD is intended to process (see [6.2](#)). The items chosen shall be those with the greatest mass, highest specific heat, and lowest thermal conductivity.

6.6 Chemical dosing tests

6.6.1 General

The tests shall be performed in accordance with ISO 15883-1:2006+A1:2014, 6.9.

6.6.2 Reused process chemicals

If the WD is designed to reuse a detergent and/or disinfectant solution, before use for the last permitted cycle the solution shall be above the minimum effective concentration (see [4.2.4](#) and [4.3.4](#)). The determination of chemical concentration is performed in accordance with a method given for the process chemical(s). Record whether the requirements are fulfilled.

6.7 Tests of cleaning efficacy

6.7.1 General

The conditions of use of cleaning solutions within the WD shall be within the conditions validated and specified as acceptable.

Tests conducted on cleaning solutions shall be carried out at the end (or simulated end) of the shelf life after it has been stored under the worst case recommended storage conditions.

The test procedure and test loads are designed to demonstrate compliance with the requirements of cleaning efficacy in accordance with ISO 15883-1:2006+A1:2014, 6.10, but take into consideration the nature of the loads and, if applicable, combination of cleaning/disinfection in a single stage.

The determination of cleaning efficacy shall be made on the defined cleaning stage only. To claim that particular load(s) can be processed in the WD, data shall be required to establish that those load(s) can be effectively cleaned in the WD.

6.7.2 Materials

6.7.2.1 Load carrier

The load carrier chosen for the test load shall be of the type recommended for the devices to be processed (see [6.2](#)).

6.7.2.2 Test loads

The type test shall be carried out using the loads described in [6.2](#).

6.7.2.3 Test soils

Devices to constitute a test load shall be contaminated with one or more test soils by the method given in ISO/TS 15883-5 that are pertinent to the load being processed.

NOTE 1 Local requirements can specify the use of particular test soils and methods.

NOTE 2 The attention of manufacturers is drawn to the user's choice of test soils(s) and method(s) for operational testing; this can indicate a need to carry out similar testing before the WD is supplied.

The test soils used for the load, chamber wall, and load carriers may be the same or different. Where different test soils are used, the rationale for the choice of test soil shall be documented.

6.7.2.4 Water quality

If the efficacy of the cleaning solution is liable to be impaired by dilution with water above a certain level of hardness, then testing shall be carried out with a cleaning solution prepared by dilution with water at the maximum permitted hardness.

6.7.3 Procedure

Place the test load contaminated with the test soil in the chamber. Start a normal cleaning cycle for the load type under test. Interrupt the cycle after the cleaning stage and, if applicable, just prior to the start of the disinfection stage. A rinse with water may be provided after cleaning if defined as part of the cycle. If a cycle with a combined cleaning and disinfecting stage is designed, interrupt the cycle after that combined stage and any rinse. Examine the test load visually and additionally by a method given in ISO/TS 15883-5 for the particular test soil used for the presence of residual soil. Residual soil detection should also be confirmed by a qualitative or semi-quantitative version of methods given in ISO 15883-1:2006+A1:2014, Annex C.

6.7.4 Results

Record the adequacy of the cleaning process using the criteria specified for the particular test soil used in ISO/TS 15883-5 and additionally the detection results for the method uses in accordance with ISO 15883-1:2006/Amd 1:2014, Annex C.

6.8 Test of disinfection efficacy

6.8.1 General

The conditions of use of disinfectant(s) in the WD shall be within the validated and specified conditions.

Tests conducted on disinfectants shall be carried out at the end (or simulated end) of the shelf life after the disinfectant has been stored under the worst case storage conditions.

National regulatory requirements can specify approval procedures prior to the use of a disinfectant in WDs for medical devices. Compliance with these national requirements shall be deemed necessary within the territory where they apply.

6.8.2 Preliminary tests on chemical disinfectants

6.8.2.1 General

An initial series of tests, as set out in [4.3](#), intended to verify the *in vitro* microbicidal efficacy of the disinfectant solution under conditions identical to those which will be applied at the time of the cycle's disinfection phase, shall be carried out unless adequate data under relevant conditions can be supplied for shorter contact time(s).

For this, the microbicidal efficacy of the disinfectant solution shall be verified.

During these tests, experimental conditions intended to simulate the conditions within the WD shall be used.

6.8.2.2 Concentration

The disinfectant shall be tested at the minimum concentration available during the disinfection phase of the cycle, based on the minimum recommended concentration (MRC).

Each disinfectant recommended for use in the WD shall be tested.

In the case where it is intended that a disinfectant solution be reused, the efficacy of the solution shall be determined as a function of its minimum effective concentration (MEC) (see [4.3.4](#)).

6.8.2.3 Temperature

Two cases shall be considered:

- a) if the disinfection stage is carried out under uncontrolled temperature conditions, the test temperature shall be the minimum and maximum temperature permitted during the cycle's disinfection phase;
- b) if the disinfection stage is carried out under temperature controlled conditions, the test temperature shall correspond to the lower and upper limit disinfection temperature.

6.8.2.4 Contact time

The contact time observed during the tests shall be the minimum duration of the disinfection stage.

6.8.2.5 Water quality

If the efficacy of the disinfectant is liable to be impaired by dilution with water above a certain level of hardness, then testing shall be carried out with the disinfectant prepared by dilution with water at the maximum permitted hardness.

6.8.2.6 Neutralization

Before an investigation of the efficacy of the disinfectant, a method of neutralizing the disinfectant at the end of the exposure period shall be demonstrated and documented. This shall include demonstration that, for any neutralizing agent used, neither the neutralizing agent nor any reaction products with the disinfectant are microbicidal or inhibit the growth of the test organism. When a secondary host such as a cell culture is used as the detection system for the survival of test organisms, the absence of carry over effects on the cell culture system and detection of low numbers of test organisms added as a challenge to the test system shall be demonstrated.

6.8.2.7 Test organisms

Test organisms shall be selected on the basis of antimicrobial claims made with the WD, with consideration of [4.3](#).

NOTE Guidance on choice of organisms can be obtained from relevant published method standards or generally accepted national guidelines on surface disinfectant efficacy testing, e.g. EN 13624, EN 13727, EN 14348, EN 14476, AOAC International (2012), RKI/DVV guideline (2008).

6.8.2.8 Presentation of test organisms

While initial potency tests may be carried out using a suspension of test organisms, the demonstration of efficacy on contaminated surfaces shall be required. The surfaces of the test pieces to be inoculated with test organisms shall be representative of those found in the WD chamber and the devices to be processed.

6.8.2.9 Detection of test organisms

The culture method used to enumerate the number of surviving microorganisms after exposure to the disinfectant shall be validated. The culture method shall be capable of recovering a low number (approximately 10) of the organisms for which it is intended to be used.

6.8.3 Self-disinfection tests

6.8.3.1 Type test

The type test is intended to verify that the WD "self-disinfection" mode will disinfect those parts of the WD which come into contact with fluids which are intended to, or can, contact the load.

The test method used shall provide an estimate of the bacterial levels in the final rinse water at the end of a normal operating cycle following the self-disinfection cycle (see Annex C).

In addition, thermometric verification of A_0 attainment shall be performed for thermal self-disinfection cycles in accordance with ISO 15883-1:2006+A1:2014, 6.8.

6.8.3.2 Operational and routine test

The test method used shall estimate the bacterial levels in the final rinse water at the end of a normal operating cycle following the self-disinfection cycle (see Annex C).

NOTE The test on the final rinse water can be sufficient to verify the self-disinfection cycle. The sample can be taken from any suitable point that ensures the water is collected following circulation through the components being disinfected.

6.8.4 Chemical disinfection of the load

6.8.4.1 Type test

The test shall be carried out in accordance with Annex D.

The test method shall use a load in accordance with [6.2](#), with specific load examples given in Annex E.

A range of other microorganisms can be used in combination with a soil relevant to the load from ISO/TS 15883-5.

NOTE A particular test organism is suggested but others can be used at the request of the user.

Mechanical removal alone (i.e. wash-off) shall be evaluated in the absence of the disinfectant.

6.8.4.2 Operational and performance qualification tests

Operational and performance tests shall establish the levels of all controlling variables that affect the disinfection of the load are within the limits established during type testing.

NOTE When required by national regulation, specified test loads can be used to simulate the range of load items. Direct inoculation of test organisms, biological indicators, or bioburden testing (ISO 11737-1) can be used to monitor the efficacy of the disinfection process. Microorganisms incorporated into test soils can be used instead of, or as well as, the use of inoculated test objects (see ISO/TS 15883-5).

6.8.4.3 Routine tests

Routine tests shall establish the levels of all controlling variables that affect the disinfection of the load are within the limits established during type testing.

7 Documentation

Documentation shall be in accordance with ISO 15883-1:2006/Amd 1:2014, Clause 7.

8 Information to be provided by the manufacturer

In addition to the information specified in ISO 15883-1:2006/Amd 1:2014, Clause 8, the following information shall be provided:

- a) range of load supports available and required;
- b) details of which parts of the WD are subjected to disinfection during the disinfection stage and self-disinfection cycle and which parts are not; guidance on the frequency at which any water treatment equipment that is part of the WD shall be disinfected;

- c) locations of temperature sensors being representative of the lowest temperature of the system;
- d) the detergent(s) and disinfectant(s) used in the type testing;
- e) recommendations to the user for the maximum period or number of operating cycles for which the reusable detergent(s) and/or disinfectant(s) may be used;
- f) the range of antimicrobial activity (e.g. bactericidal, virucidal, fungicidal, mycobactericidal);
- g) a method for the user to monitor the disinfectant using a chemical indicator or other method specific for the disinfectant to show that the disinfectant is at or above the minimum effective recommended concentration;
- h) maximum time required for the WD to be ready for use on start-up at minimum utilities;
- i) if the water treatment equipment is not part of the WD, the requirements for water supplied to the WD including the requirement to control the microbial contamination of the water supply (see [4.7](#)).

9 Marking, labelling, and packaging

The WD shall be marked externally in accordance with the requirements of IEC 61010-2-040:2005, Clause 5.

10 Information to be requested from the purchaser by the manufacturer

The requirements of ISO 15883-1:2006+A1:2014, Clause 10 apply.

Annex A (normative)

Summary of test programmes

Table A.1 — Summary of tests in addition to ISO 15883-1:2006/Amd 1:2014

Brief description of test	Requirement Clause	Test Clause	Type test	Work s test	OQ	PQ	Routine test
Accuracy of the dosing system	4.1.4	6.6	X	X	X	B	X (Q)
Cleaning efficacy	4.2.3	6.7	X	B	B	X	X(D)
Detergent reuse	4.2.4	6.6.2	X	B	B	X	X (D)
Disinfectant reuse	4.3.4	6.6.2	X	B	B	X	X (D)
Load disinfection efficacy	4.3	6.8.4	X	B	X	X	X (D)
Chemical disinfectant	4.3.2	6.8.2	X	B	B	B	B
Final rinsing	4.4	6.3	O	B	B	X	X (Y)
Self-disinfection	4.5.4	6.8.3	X	B	B	X	X (Y)
Chemical Self-disinfection	4.5.6	Annex B	X	B	O	B	B
Drying	4.6	6.4	X	B	X	B	X (D)
Water treatment equipment	4.7	6.3	X	B	B	X	X (Y)
Chemical dosing							
Accuracy and repeatability	in accordance with ISO 15883-1:2006 +A1:2014, 5.7.5	in accordance with ISO 15883-1:2006 +A1:2014, 6.9.1	X	—	—	X	—
Low level indicator	in accordance with ISO 15883-1:2006 +A1:2014, 5.7.6	in accordance with ISO 15883-1:2006 +A1:2014, 6.9.2	X	X	X	X	—
Concentration determination			X	—	X	X	—
Instrumentation							
Legibility	in accordance with ISO 15883-1:2006 +A1:2014, 5.12.3	in accordance with ISO 15883-1:2006 +A1:2014, 6.6.2	X	—	—	—	—
Calibration	in accordance with ISO 15883-1:2006 +A1:2014, 5.11, 5.12.4, 5.13, 5.14 and 5.15	in accordance with ISO 15883-1:2006 +A1:2014, 6.6.1	V	—	—	V	—

X recommended

B not recommended

O optional test which can be requested by the purchaser or user

V verification of calibration at the value(s) of interest for the particular instrument, e.g. the disinfection temperature

Q quarterly test interval, Y yearly test interval, D daily test interval

Table A.1 (continued)

Brief description of test	Requirement Clause	Test Clause	Type test	Work s test	OQ	PQ	Routine test
Fault indication	in accordance with ISO 15883-1:2006 +A1:2014, 5.22.1 and 5.4.1.5	in accordance with ISO 15883-1:2006 +A1:2014, 6.3.5, 6.3.6, 6.3.7 and 6.3.8	X	—	X	—	—
X recommended B not recommended O optional test which can be requested by the purchaser or user V verification of calibration at the value(s) of interest for the particular instrument, e.g. the disinfection temperature Q quarterly test interval, Y yearly test interval, D daily test interval							

The tests included in [Table A.1](#) assume that all necessary installation qualification checks and tests have been completed satisfactorily.

Optional tests may be carried out at the discretion of the purchaser/user or can be required by local regulation.

Test intervals suggested are given for guidance only. Individual programmes of routine tests should be defined on the basis of a risk analysis, taking into account the conditions and reliability of the WD, the extent of independent monitoring of each cycle, and the use to which the WD is put.

Annex B (normative)

Methods for microbiological evaluation of disinfection of liquid transport system

B.1 General

The following two methods are intended to simulate various incidents that might arise during normal use of the WD and that could give rise to contamination of the WD (see 4.7.2 and 6.3).

Method 1 (specified in B.5.2.1) tests the self-disinfection cycle after a simulated malfunction of the internal water treatment equipment that, although repaired quickly (24 h later), has caused contamination of the WD by the microorganisms present in the supply water.

Method 2 (specified in B.5.2.2) also simulates the case of WD contamination by microorganisms present in the supply water following a malfunction of the internal water treatment equipment. However, in this case, the self-disinfection cycle is only applied one week after a water equipment malfunction, and that during this week the WD has continued to be used (one load washing/disinfection cycle per day). This allows evaluation of the efficacy of the self-disinfection cycle of a potentially contaminated WD after one week of use.

Moreover, monitoring the internal level of contamination of the WD during the interval of time between the water treatment equipment failure and the execution of the self-disinfection cycle will allow evaluation of whether the WD's design is effective in limiting the development of microorganisms in the pipes of the WD.

B.2 Apparatus and reagents

B.2.1 Washer-disinfector.

B.2.2 *Pseudomonas aeruginosa* (for example, ATCC 15442¹) or equivalent) as microorganism.

B.2.3 **Bacterial suspension**, with 1 CFU/ml × 10⁹ CFU/ml to 1 CFU/ml × 10¹⁰ CFU/ml in sterile distilled water.

B.2.4 **Tryptone soya agar (TSA)**, as maintenance and counting medium (see EN 13727).

B.3 Cycles

B.3.1 General

The following cycles shall be available:

- WD cycle;
- self-disinfection cycle;

1) ATCC American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209, USA, www.attc.org. The ATCC number is the collection numbers of strains supplied by these culture collections. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named.

- sampling cycle;
- contamination cycle.

B.3.2 Sampling cycle

The sampling cycle shall correspond to a routine cleaning and disinfection cycle interrupted during the stage before disinfection, and for which the detergent shall be replaced by sterile distilled water. Once the cycle has been interrupted, a sample from the bottom of the tank containing water having circulated in the WD's pipe work shall be taken.

NOTE This sampling programme only includes the cleaning and rinsing phase and circulates water throughout the WD's pipe work, without there being any addition of disinfectant or detergent product.

If the cycle cannot be interrupted immediately prior to the disinfection stage, then a complete cycle substituting sterile purified (e.g. reverse osmoses) water for all process chemical solutions shall be used.

B.3.3 Contamination cycle

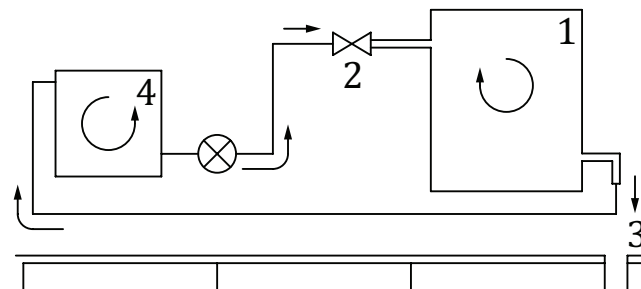
This special programme corresponds to a routine cleaning and disinfection cycle for which

- the disinfectant solution heating system (if fitted) is deactivated, and
- the detergent and disinfectant are replaced by sterile distilled water.

During this contamination cycle, the WD is connected to the external tank containing the contamination solution (see [Figure B.1](#)), so that during each phase of the contamination cycle, the WD is only fed with the contamination solution contained in the external tank.

B.4 Connection of the WD to the external tank

The connection of the WD to the external tank shall be as shown in [Figure B.1](#).



Key

- 1 WD
- 2 water supply
- 3 drainage
- 4 external tank

NOTE As a function of manufacturer's recommendations, external peripherals can be inserted between the water supply network and the WD (water softener, etc.).

Figure B.1 — Connection of the WD to the external tank — Test configuration

B.5 Procedure

B.5.1 General

B.5.1.1 External tank disinfection

Before each test, subject the external tank in which the contamination solution is prepared to a thermal disinfection cycle with an A_0 of not less than 600.

B.5.1.2 Verification of absence of microbiocidal residue in the external tank after disinfection

During the last rinsing stage of the external tank, collect 9 ml of the water circulating in the external tank and associated pipework.

Incorporate 1 ml of a bacterial suspension of *Pseudomonas aeruginosa* at 10^3 bacteria/ml in the previously sampled 9 ml of water.

After mixing thoroughly and 10 min of contact time, establish the number of viable bacteria present in the reaction mixture, T_N , by serial dilution and counting on a TSA agar plate.

The rinsing is only considered to be valid if [see Formula (B.1)]

$$10 \times \frac{T_N}{T_t} \geq 0,8 \quad (\text{B.1})$$

where

T_N is the number of viable bacteria present in the reaction mixture;

T_t is the exact concentration of bacteria in the bacterial suspension (control).

B.5.1.3 Preparation of the contamination solution

Fill the external tank with 30 l of tap water and 30 ml of a *Pseudomonas aeruginosa* suspension containing 10^9 CFU/ml. After thorough mixing, take a sample in order to establish, by serial dilution and counting on a TSA agar plate, the exact concentration of microorganisms in the contamination solution.

B.5.1.4 Contamination of the WD via the water supply network

After having prepared the contamination solution and deactivated the WD water treatment unit, connect the WD subjected to the tests to the external tank ([Figure B.1](#)). Then start the WD contamination cycle in order to ensure circulation of the contamination solution in all the internal piping of the WD.

B.5.1.5 Determination of the WD contamination level

During the different tests, determine the contamination level of the WD by running a sampling cycle and then establishing the concentration of microorganisms in the water having circulated in all the piping of the WD during this cycle. For this, during the sampling cycle collect 2 l of water in the tank of the WD. Filter 10 ml, 100 ml, and 1 000 ml of the 2 l of water through 0,2 μm membranes. Then rinse the membranes with 3 ml to 50 ml of sterile distilled water, placed on counting medium and incubate at 37 °C for 24 h.

After incubation, count and identify the number of colony forming units and express the results as a number of colony forming units per 100 ml.

B.5.2 Establishment of the efficacy of the disinfection of the liquid transport system

B.5.2.1 Method 1

Proceed as follows:

- a) install the WD;
- b) run a self-disinfection cycle;
- c) run a sampling cycle;
- d) determine the WD contamination level;
- e) deactivate the water treatment system (i.e. remove filter, deactivate heating system);
- f) disinfect the external tank;
- g) prepare the contamination solution;
- h) contaminate the WD via the water supply network;
- i) leave the WD at room temperature (not less than 20 °C) to incubate for 24 h;
- j) connect the WD normally;
- k) re-activate the water treatment system;
- l) run a self-disinfection cycle;
- m) run a sampling cycle;
- n) determine the contamination level of the WD in accordance with [B.5.1.5](#);
- o) if the analysis of the results shows more than 10 CFU/100 ml in the sample taken during step m), repeat steps l), m), and n) until reduction of the contamination to not more than 10 CFU/100 ml;
- p) record the number of self-disinfection cycles needed to reduce the contamination to not more than 10 CFU/100 ml.

NOTE It is not necessary to determine the contamination level before the disinfection cycle [[B.5.2.1](#), step l)], since the extent of contamination that will occur is specific to the design of the WD liquid transport system. Carrying out such sampling can also remove significant microbial contamination from the system.

B.5.2.2 Method 2

Proceed as follows:

- a) install the WD;
- b) run a self-disinfection cycle;
- c) run a sampling cycle;
- d) determine the contamination level of the WD;
- e) deactivate the water treatment system;
- f) disinfect the external tank;
- g) prepare the contamination solution;
- h) contaminate the WD via the water supply network;

- i) leave the WD at room temperature (not less than 20 °C) to incubate for 48 h;
- j) connect the WD normally;
- k) re-activate the water treatment system;
- l) run a standard cleaning and disinfection cycle;
- m) run a sampling cycle;
- n) determine the contamination level of the WD in accordance with [B.5.1.5](#);
- o) leave the WD at room temperature (not less than 20 °C) to incubate for 24 h;
- p) repeat steps l) to o) four times;
- q) run a self-disinfection cycle;
- r) run a sampling cycle;
- s) determine the contamination level of the WD in accordance with [B.5.1.5](#);
- t) if the analysis of the results shows the presence of more than 10 CFU/100 ml in the sample taken during step r), repeat steps q), r), and s) until reduction of the contamination to not more than 10 CFU/100 ml;
- u) record the number of self-disinfection cycles needed to reduce the contamination to not more than 10 CFU/100 ml.

Annex C (normative)

Tests for microbiological contamination of post-disinfection rinse water

C.1 Water samples

Sampling containers shall be 250 ml, or larger, and shall be sterile.

Swab the discharge surfaces of any sampling point thoroughly with 0,2 µm filtered 70 % iso-propanol and allow to dry by evaporation immediately before the sample is taken.

Take samples from the WD chamber and label as "WD Sample". Collect not less than 200 ml water, or as specified, from each sampling point for each test to be carried out.

Test the samples within 4 h of collection or store at 2 °C to 5 °C and test within 48 h of collection.

C.2 Test for aerobic mesophilic bacteria

Test post-disinfection rinse water for aerobic mesophilic bacteria in accordance with ISO 15883-1:2006+A1:2014, 6.4.2.4.

Annex D (normative)

Preparation and evaluation of indicators for microbiological testing of the efficacy of chemical disinfection of the load

D.1 Principles

Biological indicators shall contain *E. faecium* (for example, ATCC 6057²⁾ or equivalent) as the test organism with at least 10⁷ colony forming units (CFU) for the quantitative method or 10⁵ CFU to 10⁶ CFU for the qualitative method respectively. For the carrier, use non-absorbent material in accordance with [D.4.1](#). Suspend the test organisms in a test soil, apply them to the carrier surface, and allow them to dry.

The biological indicators shall be suitable to demonstrate the interaction of mechanical and chemical cleaning/disinfection. Mechanical removal alone (i.e. wash-off) shall be evaluated in the absence of the disinfectant.

D.2 Reagents

D.2.1 Suspension of the test organism in blood or bovine albumin and mucin (RAM), respectively in accordance with [D.3.2.1](#) and [D.3.2.2](#).

D.2.2 Tryptone Soya Agar or broth, respectively (TSA or TSB) in accordance with ISO/TS 15883-5:2005, G.2.6 and G.2.7.

D.2.3 Phosphate buffer solution consisting of the following:

- solution A: dissolve 16 g NaCl; 0,4 g KCl; 0,4 g KH₂PO₄ in 1 600 ml of distilled water;
- solution B: dissolve 0,2 g CaCl₂ in 200 ml of distilled water;
- solution C: dissolve 0,2 g MgSO₄ in 200 ml of distilled water;
- pH 7,4.

Sterilize the solutions A, B, and C and, after completion of the cooling period, mix them under sterile conditions adding the inactivation substances at the same time, if required.

D.3 Test organisms

D.3.1 General

Enterococcus faecium (for example, ATCC 6057²⁾ is recommended for the test.

Enterococcus faecium cultures shall be inoculated on new Tryptone Soya Agar (TSA) plates every 48 h. The incubation temperature shall be (36 ± 1) °C. To obtain the test organism suspension, wash the plates off using 10 ml of physiological NaCl solution. Wash the suspensions by centrifugation, followed by re-

2) ATTC American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209, USA, www.attc.org. The ATCC number is the collection numbers of strains supplied by these culture collections. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named.

suspension in NaCl solution and another centrifugation. Subsequently, the test organisms are added to the test soil [blood or bovine albumin and mucin (RAM) in accordance with [D.2](#)] corresponding to the initial volume.

The minimum total of the test organism solution (blood or RAM) shall be $1 \text{ CFU/ml} \times 10^8 \text{ CFU/ml}$ for the quantitative method or 10^6 CFU/ml to 10^7 CFU/ml for the qualitative method.

D.3.2 Test soils

D.3.2.1 For the blood test soil, use sterile defibrinated sheep blood.

D.3.2.2 For the RAM soil, dissolve 0,6 g bovine albumin and 1 g mucin in 100 ml NaCl peptone solution.

D.4 Test surfaces

D.4.1 General

As test surfaces, use plates of stainless steel, e.g. X5CrNi18-10, finish 2B, ground (2G) with grain size of approximately 80 in accordance with EN 10088-1 and EN 10088-2 with dimensions of 10 mm × 130 mm and an approximate thickness of 1,5 mm.

D.4.2 Cleaning

Test surfaces shall be cleaned in accordance with the following protocol:

- a) immerse the test surfaces in acetone ACS while swirling solution with a magnetic bar for 1 min to remove oil from the surface;
- b) transfer test surfaces to 5 % solution of an appropriate detergent and heat at 75 °C for 10 min;
- c) decant detergent solution;
- d) rinse with deionized or distilled water followed by immersion in 70 % technical grade isopropanol for 1 min to facilitate drying.

Remove the test surfaces with tweezers, cleaned as above, then place on clean, absorbent paper (e.g. filter paper) and allow to dry.

D.4.3 Contamination of the test surfaces

Use test soil samples of 0,1 ml each to distribute uniformly on an area within dimensions of 8 mm × 100 mm taking care not to contaminate the sides. The surfaces thus soiled are allowed to dry for a duration of 24 h at a temperature of $(22 \pm 1) \text{ °C}$ and a relative humidity of $(50 \pm 10) \%$.

The total per contaminated surface (at least $1 \text{ CFU} \times 10^7 \text{ CFU}$) shall be high enough for a reduction factor (RF) > 5 to be representable considering the detection limit.

D.5 Storage

The biological indicators prepared in accordance with [D.4](#) shall be stored at temperatures between 4 °C and 8 °C. They are suitable for testing as validated by the test laboratory to meet the microbial counts specified in [D.4.3](#).

D.6 Test for resistance

In order to determine the heat resistance of *Enterococcus faecium*, transfer 20 biological indicators into test tubes containing Tryptone Soya Broth (TSB) previously heated to 70 °C in a water bath. The amount of TSB shall be chosen so that the biological indicators are completely immersed.

Immerse the test tubes with the carriers in a water bath of 70 °C for 10 min and cool in iced water.

Following the subsequent incubation at a temperature of (36 ± 1) °C for 24 h, 90 % of the carriers shall show growth of test organisms.

D.7 Evaluation and acceptance criteria

D.7.1 Evaluation of the biological indicators using the quantitative method

Evaluation of the biological indicators by means of the quantitative method is preferably used for type testing.

The biological indicators are placed into the WD and subjected to a disinfection cycle. Once the cycle is completed, remove the biological indicators under aseptic working conditions and subject them to a visual control for residues of the test soil. Any residues shall be stated in the accompanying report. Transfer each biological indicator individually into 10 ml phosphate buffer solution with a pH of 7,4 with neutralization media suitable for disinfectants, if present.

Without treatment in the WD, add evaluated three positive controls to 10 ml phosphate buffer solution in accordance with [D.2](#).

Then shake the biological indicators transferred into phosphate buffer solution by means of an agitator (with a frequency of approx. 500 min⁻¹) for at least 20 min in order to recover the test organisms. Subsequently, determine the CFU from the agitated liquid by culturing on TSA for (36 ± 1) °C for 72 h. The method used (including type of culture media and determination of CFU) shall be given in the test report.

The reduction factor (RF) is calculated by Formula (D.1):

$$RF = \log_{10} CUF_1 - \log_{10} CUF_2 \quad (D.1)$$

where

RF is the reduction factor;

$\log_{10} CUF_1$ is the mean of the logarithms of the number of colony forming units of transport controls;

$\log_{10} CUF_2$ is the logarithm of the number of colony forming units of the treated test surfaces.

The performance is deemed to be sufficient when a reduction factor ≥ 5 has been achieved for all biological indicators.

The results from the testing of mechanical removal alone (i.e. wash-off in the absence of the disinfectant) shall be reported.

D.7.2 Evaluation of the biological indicators using the qualitative method

The detection of test organism is used preferably for the purposes of recurrent performance qualification.

For every examination, the colony number of 10^5 to 10^6 in 0,1 ml of the test soil shall be proven using a positive control.

Transfer the biological indicators individually into sterile tubes and send them back to the laboratory.

Incubation is carried out in Tryptone Soya Broth (TSB) at (36 ± 1) °C for 72 h; any nutrient solutions showing growth are sub-cultivated in order to detect the test organism. In case of a positive examination result, the test is required to be repeated.

The performance is deemed to be sufficient when none of the exposed biological indicators show growth.

The results from the testing of mechanical removal alone (i.e. wash-off in the absence of the disinfectant) shall be recorded.

D.7.3 Acceptance criteria

Incubate the sample volumes taken from the disinfectant solution at (36 ± 1) °C for a duration of 72 h.

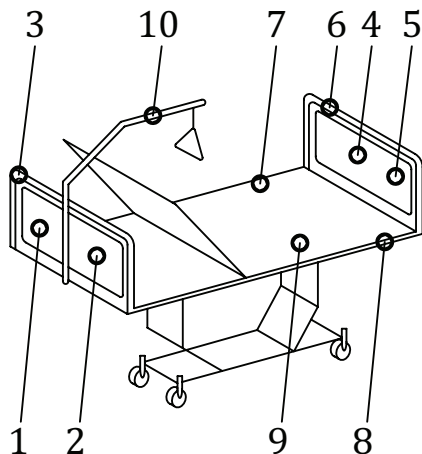
Subculture any turbid growth onto suitable nutrient media in order to detect test organisms and/or contamination if present.

The test organism shall not be detectable in the volume examined (1 000 ml or 2 volumes of 500 ml, respectively). Any observations regarding the contamination with non-test organism shall be recorded in the report.

If examination of the disinfectant solution is deemed to be required at periodic or special tests, then the test organisms shall not be detectable in sample volumes of 1 000 ml. This determination is possible only if the sample is prepared immediately.

Annex E (informative)

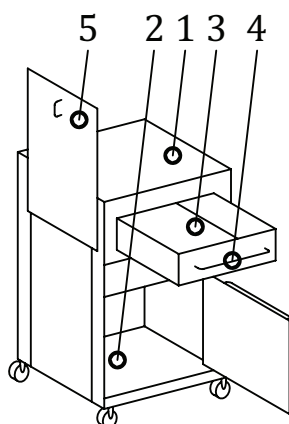
Examples of test locations for the tests with biological indicators



Key

- | | | | |
|---|------------------------|----|--|
| 1 | headboard, outer panel | 6 | footboard, rail |
| 2 | headboard, inner panel | 7 | left bed rail |
| 3 | headboard, rail | 8 | right bed rail |
| 4 | footboard, outer panel | 9 | lying area, centre |
| 5 | footboard, inner panel | 10 | ladder (if provided or if not laid down, respectively) |

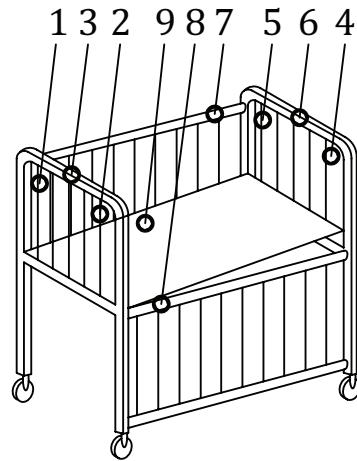
Figure E.1 — Bedframe



Key

- | | | | |
|---|----------------------------|---|-----------------|
| 1 | place of deposit | 4 | drawer, outside |
| 2 | floor area, inside, centre | 5 | folding table |
| 3 | drawer, inside | | |

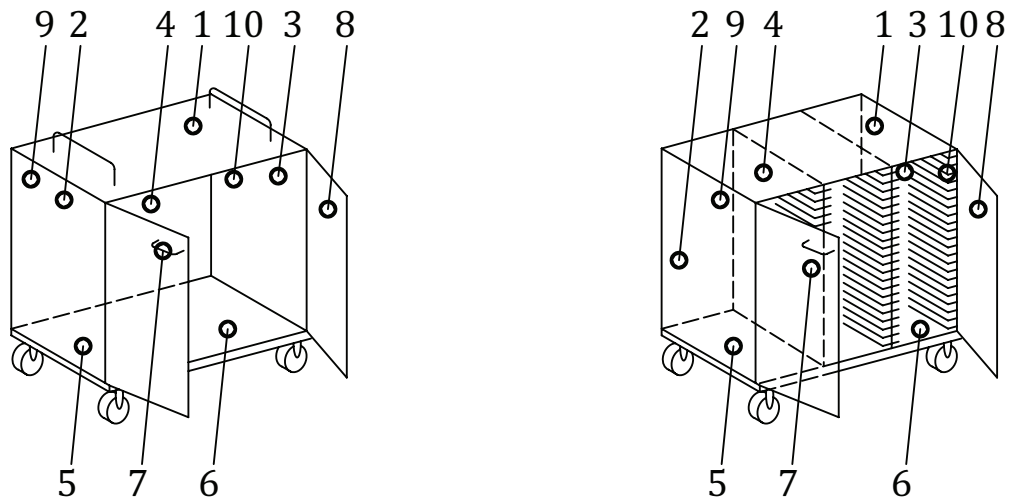
Figure E.2 — Bedside table



Key

- | | |
|---------------------------|-------------------------------|
| 1 headboard, bars outside | 6 footboard, upper rail |
| 2 headboard, bars inside | 7 side board, left rail, top |
| 3 headboard, upper rail | 8 side board, right rail, top |
| 4 footboard, bars outside | 9 lying area, centre |
| 5 footboard, bars inside | |

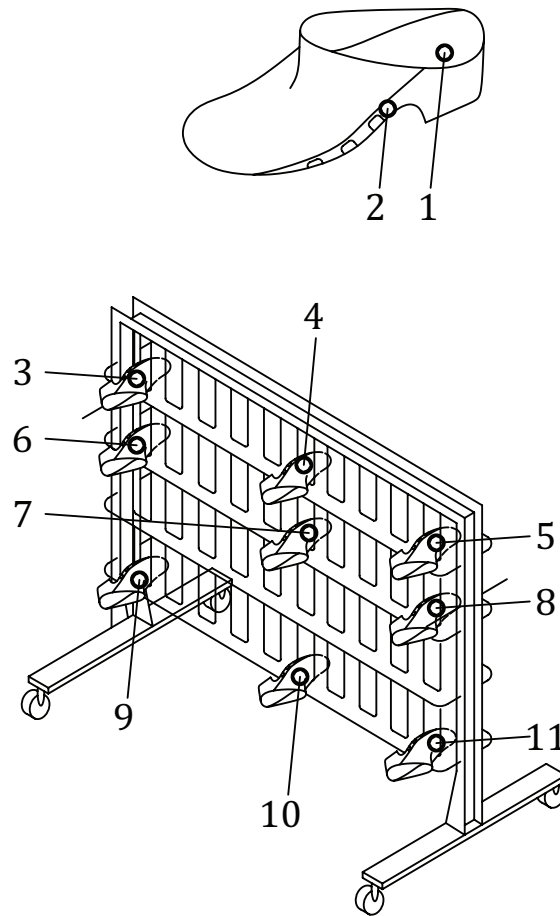
Figure E.3 — Toddler bed frame



Key

- | | |
|------------------------------|-------------------------------|
| 1 top plate, inside | 6 base plate, inside, right |
| 2 side panel, inside, left | 7 door, handle area, left |
| 3 side panel, inside, right | 8 door, handle area, right |
| 4 rear panel, inside, centre | 9 side panel, outside, left |
| 5 base plate, inside, left | 10 side panel, outside, right |

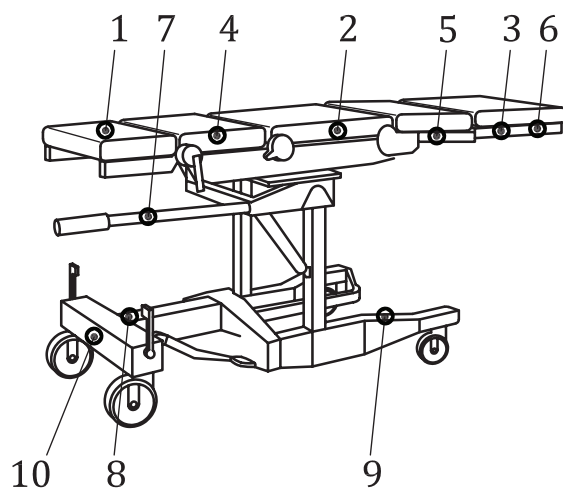
Figure E.4 — Transport carts



Key

- | | | | |
|---|-------------------------|----|--------------|
| 1 | footing, central area | 7 | centre |
| 2 | shoe sole, central area | 8 | centre right |
| 3 | top left | 9 | bottom left |
| 4 | top centre | 10 | bottom |
| 5 | top right | 11 | bottom right |
| 6 | centre left | | |

Figure E.5 — Surgical clogs and possible arrangement on loading trolley



Key

- | | | | |
|---|------------------------------------|----|------------------------|
| 1 | head section, table board, top | 6 | base frame |
| 2 | head section, table board, lateral | 7 | middle section |
| 3 | base frame (shuttle) | 8 | middle section, bottom |
| 4 | table board (top) | 9 | base frame |
| 5 | foot section, table board, bottom | 10 | middle section, bottom |

Figure E.6 — Surgical table

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BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

