



BSI Standards Publication

Washer-disinfectors

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

National foreword

This British Standard is the UK implementation of EN ISO 15883-4:2018. It supersedes BS EN ISO 15883-4:2009, which is withdrawn.

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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Amendments/corrigenda issued since publication

Date	Text affected
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English Version

**Washer-disinfectors - Part 4: Requirements and tests for
washer-disinfectors employing chemical disinfection for
thermolabile endoscopes (ISO 15883-4:2018)**

Laveurs désinfecteurs - Partie 4: Exigences et
essais pour les laveurs désinfecteurs destinés
à la désinfection chimique des endoscopes
thermolabiles (ISO 15883-4:2018)

Reinigungs-Desinfektionsgeräte - Teil 4:
Anforderungen und Prüfverfahren für Reinigungs-
Desinfektionsgeräte mit chemischer Desinfektion
für thermolabile Endoskope (ISO 15883-4:2018)

This European Standard was approved by CEN on 17 August 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

European foreword

This document (EN ISO 15883-4:2018) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" 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 June 2019, and conflicting national standards shall be withdrawn at the latest by June 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes [EN ISO 15883-4:2009](#).

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative [Annex ZA](#), which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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 14971	EN ISO 14971:2012	ISO 14971:2007
ISO 15883-1	EN ISO 15883-1:2009 + A1:2014	ISO 15883-1:2006 + Amd1:2014
ISO/TS 15883-5	CEN/ISO/TS 15883-5:2005	ISO TS 15883-5:2005
IEC 61010-2-040	EN 61010-2-040:2015	IEC 61010-2-040:2015
EN 12353	EN 12353:2013	--
EN 13727	EN 13727:2013+A2:2015	--

Endorsement notice

The text of ISO 15883-4:2018 has been approved by CEN as EN ISO 15883-4:2018 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 mandate M/023 concerning the development of European Standards related 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 Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.3, 1 st part only	4.9.2	Covered only in respect of disinfection of the incoming water treatment equipment. Aspects related to manufacturing are not covered
7.6	4.6.2, 4.9.2.3	Standard clause 4.6.2 covers ER 7.6 for the ingress of oil and particles, standard clause 4.9.2.3 for the ingress of microbes into the endoscopes being processed only. Aspects related to manufacturing are not covered.
8.1	4.1.2, 4.1.3, 4.1.5, 4.1.6, 4.1.7, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.2, 5.3, 5.4, 5.5	Covered only in respect of preventing patient and user infection by the effective reprocessing of endoscopes. Aspects related to manufacturing are not covered. The last sentence of ER 8.1 is not covered.

9.1	4.1.2, 4.1.3, 4.1.7, 4.1.8, 4.2.4, 4.8, 4.9, 5.1, 5.2	Covered only in respect of preventing patient cross infection by the effective reprocessing of endoscopes. The last sentence of ER 9.1 is not covered.
13.6 a)	8 k)	Covered for the information required in ER 13.3 j)

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 products falling within the scope of this standard.

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 EN	Remarks/Notes
1.2.1, 2 nd dash	4.2.3, 4.2.4, 4.4.4, 4.8.4	Covered in respect of leak detection and process monitoring during endoscope processing and self-disinfection procedure.
1.5.4	4.1.8, 4.2.4 a), 4.2.4 b), 8	Standard clause 4.1.8 and 4.2.4a), 4.2.4 b) cover EHSR 1.5.4 in respect of connections for process chemicals and connection systems between the WD and the endoscope only. Standard clause 8 covers EHSR 1.5.4 second paragraph only.
1.6.5	4.8, 4.9	Standard clause 4.8 covers EHSR 1.6.5 with respect to requiring a self-disinfection cycle, clause 4.9 to requiring a procedure for disinfection of the water treatment equipment to be provided.

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 products 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition ([ISO 15883-4:2008](http://www.iso.org/iso/15883-4:2008)), which has been technically revised. The main changes compared to the previous edition are as follows:

— additional annexes for establishing endoscope type test groups and endoscope product families have been included.

A list of all the parts in the ISO 15883 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This introduction is intended to be read in conjunction with the introduction to [ISO 15883-1](#).

The washer-disinfectors specified in this document are intended to process devices that can be immersed in water or aqueous solutions. For some devices this will require that, prior to processing, relevant parts of the device are protected from immersion in accordance with the device manufacturer's operating instructions.

Fields of application within the scope of the ISO series include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for washer-disinfectors for other applications are specified in other parts of ISO 15883.

Safety requirements for washer-disinfectors are given in [IEC 61010-2-040](#).

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector and its intended use, it is noteworthy that:

- a) until verifiable international criteria are adopted, the existing national regulations concerning the use and/or characteristics of the washer-disinfectors remain in force, and
- b) the ISO 15883 series provides no information as to whether the washer-disinfectors can be used without restriction in any of the ISO member states.

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Washer-disinfectors —

Part 4:

Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

1 Scope

This document specifies the particular requirements, including performance criteria for washer-disinfectors (WD) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

This document also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which can be required to achieve the necessary performance criteria.

The methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring, and requalification of WD periodically and after essential repairs, are also specified.

NOTE 1 In addition, [Annex A](#) gives guidance on an appropriate division of responsibility for the range of activities covered by this document.

NOTE 2 WD complying with this document can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended and validated this method of disinfection.

WD complying with the requirements of this document are not intended for cleaning and disinfection of medical devices, including endoscopic accessories, which are heat stable and can be disinfected or sterilized by thermal methods (see ISO 15883-1:2006+Amd 1:2014, 4.1.5).

The specified performance requirements of this document do not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 3 If it is considered that prion protein might be present, particular care is needed in the choice of cleaning agents and disinfectants to ensure that the chemicals used do not react with the prion protein and/or other protein in a manner that can inhibit its removal or inactivation from the load or washer-disinfector.

NOTE 4 This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of the WD, manufacturers of endoscopes, cleaning products, and disinfecting products.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

[ISO 14971](#), *Medical devices — Application of risk management to medical devices*

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

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

[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*

[EN 12353](#), *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

[EN 13727](#), *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in [ISO 15883-1](#) and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

air break

physical separation in water supply pipes to prevent back flow from equipment

[SOURCE: ISO 11139:2018, 3.8]

3.2

analyte

chemical substance that is the subject of chemical analysis

[SOURCE: ISO 11139:2018, 3.12]

3.3

block

<endoscope> group of channels comprising part of an endoscope with specified lengths, diameters and interconnections

[SOURCE: ISO 11139:2018, 3.30]

3.4

channel separator

<endoscope> device used to keep apart interconnected fluid pathways

EXAMPLE A device inserted in a trumpet valve cylinder where multiple channels meet in order to separate the air and water pathways in the air/water valve assembly.

[SOURCE: ISO 11139:2018, 3.40]

3.5

colony forming unit

CFU

visible aggregation of microorganisms arising from a single cell or multiple cells

[SOURCE: ISO 11139:2018, 3.53]

3.6

disinfecting agent

physical or chemical agent used for disinfection

[SOURCE: ISO 11139:2018, 3.83]

3.7

disinfection

process to inactivate viable microorganisms to a level previously specified as appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

3.8

endoscope connector

device to interface with the fluid entry port of a channel of an endoscope that, where applicable, includes the tubing connected to the channel irrigation system of the washer-disinfector

[SOURCE: ISO 11139:2018, 3.94]

3.9

endoscope leak test

set of actions to identify a loss of integrity

Note 1 to entry: The test is intended to establish that the surface covering the device and/or lining a device channel is intact to the extent necessary to maintain a slightly positive pressure.

[SOURCE: ISO 11139:2018, 3.95, modified — Note 1 to entry has been added.]

3.10

endoscope port

part of an endoscope to which the irrigation system of the washer-disinfector is connected to irrigate all or part of a channel

[SOURCE: ISO 11139:2018, 3.96]

3.11

endoscope product family

group of endoscopes with comparable design, including the number, construction and purpose of the different endoscope channels

[SOURCE: ISO 11139:2018, 3.97]

3.12

endoscope surrogate device

item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in endoscope channels

Note 1 to entry: Elements can include channel length and diameter, connectors, channel separators, port closures, return valves, etc.

[SOURCE: ISO 11139:2018, 3.98]

3.13

endoscope type test group

endoscopes for which the general channel design and specific characteristics affecting the flow conditions in the endoscope are similar

Note 1 to entry: The general channel design includes lengths and diameters. Characteristics affecting the flow conditions in the endoscope are, for example, connectors, channel separators, port closures, return valves.

Note 2 to entry: Similar implies that small variations can be possible. Endoscopes that show small variations in channel specifications that do not lead to a significant variation in the flow and pressure characteristic through the channels could be in the same endoscope type test group.

[SOURCE: ISO 11139:2018, 3.99]

3.14

inoculated carrier

supporting material on or in which a specified number of viable test microorganisms has been deposited

[SOURCE: ISO 11139:2018, 3.144]

3.15

irrigation plan

<endoscope washer-disinfector> stipulated direction of flow of process fluids through the specified channels of an endoscope

[SOURCE: ISO 11139:2018, 3.148]

3.16

liquid transport systems

<washer-disinfector> components of equipment used to store, pump or transport water and/or solutions, excluding pipework before the air break

[SOURCE: ISO 11139:2018, 3.154]

3.17

microbial inactivation factor

measured change in microbial population caused by the lethal effect of the disinfection or sterilization process

Note 1 to entry: It is expressed as $\log_{10}$.

[SOURCE: ISO 11139:2018, 3.173]

3.18

microbial reduction factor

extent to which the bioburden is reduced in tenfold increments

Note 1 to entry: It is expressed as $\log_{10}$.

Note 2 to entry: This can be caused by the combination of the microbial inactivation factor and the physical removal of microorganisms.

[SOURCE: ISO 11139:2018, 3.174, modified — Note 2 to entry has been added.]

3.19

microbial resistance

ability of a microorganism or population of microorganisms to withstand a microbial reduction process

Note 1 to entry: This refers to resistance of microorganisms to disinfectants used in a WD.

[SOURCE: ISO 11139:2018, 3.175, modified — Note 1 to entry has been added.]

3.20

minimum effective concentration

MEC

lowest concentration of a chemical or product, used in a specified process, that achieves a claimed activity

[SOURCE: ISO 11139:2018, 3.177]

3.21

minimum recommended concentration

MRC

lowest concentration of a chemical or product specified for use in a process

[SOURCE: ISO 11139:2018, 3.178]

3.22

obstruction

<endoscope channel> partial or complete blockage

[SOURCE: ISO 11139:2018, 3.187]

3.23

port closure

<endoscope> device to close an endoscope port during processing in order to maintain the flow of process fluids throughout the length of the endoscope

EXAMPLE To close the suction valve port.

[SOURCE: ISO 11139:2018, 3.198]

3.24

self-disinfection cycle

operating cycle intended to disinfect all liquid transport systems' piping, chamber(s), tanks and other components which come into contact with the water and/or solutions used for cleaning, disinfecting and rinsing the load

Note 1 to entry: The self-disinfection cycle is used without a load in a washer-disinfector.

[SOURCE: ISO 11139:2018, 3.249]

3.25

thermolabile

readily damaged by heat

[SOURCE: ISO 11139:2018, 3.302]

3.26

washer-disinfector accessory

items or attachments, including connectors, required to process a medical device in a washer-disinfector

[SOURCE: ISO 11139:2018, 3.320]

4 Performance requirements

4.1 General

4.1.1 The WD shall conform to ISO 15883-1:2006+Amd 1:2014 with the exception of the following subclauses:

- a) 4.2.3 (washing stage, modified by [4.3.3](#) of this document);
- b) 4.3.1 (specification for thermal disinfection of the load carrier and chamber walls during a standard cleaning and disinfection cycle is not applicable to this document);
- c) 4.3.3 (chemical and thermal disinfection, modified by [5.4](#) of this document);
- d) 5.3.2.5 (microbial quality of final rinse water, modified by [4.5](#) of this document);
- e) 5.11.4 (process verification, modified by [5.6](#) of this document);
- f) 6.4.2.1 (test for quality of final rinse water – sampling, modified by [6.3](#) and [Annex E](#) of this document);
- g) 6.5.6 (test for chamber venting to prevent pressurization by steam is not applicable to this document);

- h) 6.8.2 (load temperature test, modified by [6.9.1](#) of this document);
- i) 6.8.3 (chamber wall temperature test, replaced by [6.9.1](#) of this document);
- j) 6.10.2 (cleaning efficacy test 1; modified by [6.11](#) of this document).

Means shall be provided to position temperature sensors for test purposes. Depending on the type of washer design the manufacturer can decide to follow ISO 15883-1:2006+Amd 1:2014, 5.1.11 or provide an alternative solution better fit to the purpose.

4.1.2 Each device, including any device channels and/or cavities, shall be processed by the WD as follows:

- a) leak testing (where appropriate) in accordance with [4.2](#);
- b) cleaning (which may include several stages) in accordance with [4.3](#);
- c) disinfecting in accordance with [4.4](#);
- d) final rinsing in accordance with [4.5](#);
- e) purging of rinse water in accordance with [4.6](#);
- f) drying (when appropriate) in accordance with [4.7](#).

4.1.3 After the complete process in the WD the endoscope shall be safe for its intended use. The combination of the cleaning, disinfection and rinsing process shall be designed to achieve this condition, recognizing the high level of microbial and other contamination that might exist, see References [\[33\]](#), [\[34\]](#) and [\[35\]](#). It shall be necessary to take into account other factors such as the design of connectors. This capability shall be demonstrated during type testing for endoscopes that the WD is designed to process [see also [8 a\)](#), [8 b\)](#) and [8 c\)](#)].

Where the disinfection of the water supplied to the WD is performed by adding a low dosage of a disinfectant to the water, compliance with this document shall be demonstrated with and without the water disinfectant. Any variation in water disinfectant concentration due to local environmental conditions that might change the result of the test shall be taken into account.

Demonstration of the capability of the complete cycle efficacy shall be provided during additional type testing by employing a modification of the methods described in [Annex B](#) with added test soil and/or ISO/TS 15883-5:2005, Annex I, using the organism(s) previously established during *in vitro* tests as most resistant to the disinfectant under in-use conditions and on endoscopes that are representative for each relevant endoscope type test group [see [8 a\)](#) and [Annex H](#)].

According to the nature of the most resistant microorganism selected the minimum log₁₀ reduction obtained after a complete standard cycle for that microorganism(s) shall be:

- 9 log₁₀ for vegetative bacteria;
- 6 log₁₀ for fungal spores;
- 6 log₁₀ for mycobacteria; or
- 4 log₁₀ for bacterial endospores.

NOTE 1 In order to limit the work load the type tests can be performed on representative endoscopes from endoscope type test groups (see [Annex H](#) to establish relevant endoscope type test groups).

NOTE 2 The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include:

- a) the nature (characteristics) of the device being processed;
- b) the extent and nature of the soiling to be removed;

- c) the temperature of the process;
- d) the mechanical energy (type, output);
- e) purging to remove rinse water;
- f) the detergent system;
- g) the nature, volume, concentration and temperature of the cleaning and disinfectant solutions and their ability to wet the surfaces to be cleaned and disinfected;
- h) the duration of the various process stages;
- i) the removal of suspended soil.

4.1.4 The instructions for use of the WD shall recommend that the actions necessary to ensure effective and safe processing of the endoscope and its accessories in the WD be followed, e.g. leak testing, any pre-treatment, manual cleaning and/or disassembly, of the endoscope [see 8 k) 8)].

It shall be specified, which of the pre-treatment steps, as listed in the endoscope manufacturer's processing instructions for use, shall be performed in order to ensure effective and safe processing of the endoscope.

NOTE National guidelines can require certain pre-cleaning steps (e.g. brushing of endoscopes channels prior to processing inside WD).

4.1.5 The value of any process variable that affects the efficacy of the cycle shall be pre-set and adjustment shall require the use of a key, code or tool (see also ISO 15883-1:2006+Amd 1:2014, 5.18.3, 5.18.8 and 5.18.12).

4.1.6 The means to control the total volume of water admitted per stage shall be controlled to a manufacturer defined level of accuracy.

4.1.7 The means to control the volume of process chemicals admitted shall deliver the set volume to an accuracy of $\pm 5\%$ or better.

4.1.8 When the WD uses two or more different process chemicals, means other than labelling and/or colour coding alone of connectors, containers and/or tubing, shall be provided to ensure that connection is made to the correct container of process chemical.

4.1.9 The instructions for use of the WD shall include a recommendation that heat-stable endoscopic accessories for thermolabile medical devices should be thermally disinfected and/or sterilized.

4.1.10 The design of the washer-disinfector or any device or washer-disinfector accessories provided with the WD shall not impair the quality of the water supplying the WD.

4.2 Systems for leak testing

4.2.1 These requirements shall apply only to WD intended to process endoscopes that require a test to verify that the device is watertight.

NOTE This test is intended to demonstrate that the endoscope will not be damaged by liquid ingress during the WD operating cycle. It is regarded only as a test of the integrity of the endoscope when all parameters of the WD leak test (e.g. pressure, duration, maximum leak accepted) are consistent with those specified for the endoscope.

4.2.2 The WD shall be provided with either:

- a) means to carry out an automatic leak test on the endoscope which shall be completed before the load comes into contact with process fluids in the WD;

or

- b) instructions for use that include the requirement to carry out the test manually prior to processing through the WD.

NOTE 1 An alternative method specified for the endoscope can be used for determining the integrity of the endoscope when appropriate.

NOTE 2 WD with an automatic leak test can include a user selectable option to repeat the leak test at the end of the process and/or independently of a normal process cycle.

NOTE 3 An automated leak test is the preferred option.

4.2.3 For WD having an automatic leak test, the automatic controller shall prevent the continuation of the operating cycle and operate an audible and visible alarm indicating a leak test failure if a leak is detected in an endoscope.

Variations in temperature that might adversely affect the sensitivity of the leak test and the temperature range permitted in the WD during the automatic leak test, if fitted, shall be stated [see 8 g)].

NOTE 1 A leak test failure indicates that the device is likely to be damaged by further processing. However, a satisfactory leak test does not provide absolute assurance that the device will not be damaged by further processing.

NOTE 2 An automatic leak test which maintains a positive pressure throughout the cycle can provide an additional safety level.

4.2.4 In WD provided with an automatic leak test:

- a) the WD shall be designed so that the connectors provided for irrigation of the endoscope channel(s) cannot be connected to the endoscope leak test connection port on the endoscope;
- b) the connection system between the endoscope and the WD shall be designed so that the leak test connector on the WD cannot be connected to the endoscope channel(s) to be irrigated;
- c) the means used to monitor the pressure inside the device (e.g. pressure transducer) shall be independent from the means used to control the pressure applied to the endoscope to perform the leak test (e.g. pressure regulating valve);
- d) the system used to pressurize the device during each leak test shall be provided with a means of preventing over-pressurization of the device in the event of failure of the pressure control system;
- e) the extent and duration of pressurization and the pressure drop or air flow which will be used to indicate a failure shall be either in accordance with the device manufacturer's instructions for the devices that the WD is intended to process, or independently verified.

4.2.5 For WD with an automatic leak test, means shall be provided to automatically warn the user with an audible and/or visible alarm after the initiation of the operating cycle if the leak test connectors are not connected to the endoscopes.

4.2.6 WD with an automatic leak test shall be tested in accordance with 6.5.

4.3 Cleaning

4.3.1 General

All surfaces (internal and external) of the endoscope(s) which are required to be disinfected by the WD shall be cleaned (see [6.11](#) of this document, and ISO 15883-1:2006+Amd 1:2014, 4.2.1.1, 5.1.10).

Some endoscope(s) have components (e.g. electronic connectors) that their manufacturer recommends cannot be immersed in water or aqueous solutions. These component parts should be processed in accordance with the manufacturer's instructions and then protected from immersion during processing in the WD.

Cleaning shall comprise washing with a detergent solution that may, when necessary, be preceded by flushing. Washing shall be followed by rinsing unless the conditions specified in [4.3.4](#) have been met.

4.3.2 Flushing

When necessary, the WD shall provide means to flush the internal and external surfaces of the endoscope.

NOTE Flushing before washing might be necessary to eliminate soils or to avoid any interaction between the chemicals used during pre-treatment and those of the WD processing cycle.

The flushing water or solution shall be discharged during or after each operating cycle and shall not be re-used.

4.3.3 Washing

The detergent(s) to be used shall be specified, as established during type testing; additional detergents may be used if established by further type testing [see [8 n](#)].

The detergent solution shall be discharged during or after each operating cycle and shall not be re-used.

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

This shall be achieved either:

- a) by controlling the temperature of the detergent solution;
- or
- b) where appropriate, by operating the WD at ambient temperature with a means of preventing operation of the WD when the detergent temperature is outside the specified temperature range.

4.3.4 Post-washing rinsing

Rinsing between washing and disinfection shall be used to reduce the concentration of residues (process chemicals and soiling including microbial contamination) to a level that does not impair the efficacy of the disinfection stage.

Rinsing shall take place between washing and disinfection unless it can be demonstrated that:

- a) there is no adverse reaction between process chemicals being used for each of these stages;
- b) there is no adverse reaction between suspended or residual soiling and the disinfectant that can compromise the disinfection stage.

The rinse water quality shall be specified. This shall be of, at least, potable quality [see [8 q](#)].

4.3.5 Determination of cleaning efficacy

Cleaning efficacy shall be determined in accordance with [6.11](#).

4.4 Disinfecting

4.4.1 General

National regulatory requirements can specify approval procedures for disinfectants to be used in WD for medical devices. Compliance with these national requirements shall be deemed to meet the requirements of [4.4](#) within the territory where these requirements apply.

The capability of the WD to provide disinfection of the device shall be deemed to have been established if, when the WD is tested as specified in [6.12.6](#) under the specified conditions of disinfectant concentration, volume, temperature and contact time, the required microbial inactivation factor is attained (see [4.4.2.5](#)).

The choice of disinfectant shall ensure that the spectrum of activity is appropriate for the intended use.

The efficacy of disinfectants can be seriously impaired by residual soiling, inorganic salts etc. remaining on the device(s) and therefore an effective cleaning prior to disinfection is necessary.

NOTE Other process chemicals, e.g. detergents can react with and seriously impair the activity of disinfectants if they are not removed before the disinfection stage.

4.4.2 Efficacy of the disinfectant

4.4.2.1 The following tests are based on the use of aqueous solutions of a disinfectant. Other systems, e.g. based on gaseous disinfectants are not excluded; equivalent tests are required.

4.4.2.2 When tested in accordance with [6.12.2](#), the bactericidal, mycobactericidal, fungicidal and virucidal *in vitro* efficacy of the disinfectant shall be demonstrated with standardized test methods under the conditions of use in the WD and, if required by national regulations, at the MEC and mandatory test conditions (e.g. potency tests – see Note 1).

The disinfectant chosen shall also be active against bacterial endospores. The disinfectant should reduce the population of bacterial endospores by not less than 6 log₁₀ within 5 h of exposure, or at an equivalent rate, under the use conditions.

NOTE 1 Demonstration by the disinfectant manufacturer that the disinfectant meets the above requirements can be made employing methods based on relevant published standards or other relevant publications, e.g. [EN 13624](#), [EN 13727](#), [EN 14348](#), [EN 14476](#), [EN 14561](#), [EN 14562](#), [EN 14885](#), [EN 14563](#), AOAC Use dilution test, ASTM E2197 virucidal test, OECD Guideline.

NOTE 2 Suitable methods include the AOAC sporicidal test (method 966.04), ASTM E2111-05, [EN 14347](#), [EN 13704](#), etc.

NOTE 3 National regulatory authorities can require different inactivation values and test methods, in which case, the tests listed in Notes 1 and 2 might need to be modified to demonstrate efficacy.

4.4.2.3 A specific neutralization method for the disinfectant shall be validated in accordance with [6.12.2.3.5](#).

NOTE These data can be provided by the disinfectant manufacturer.

4.4.2.4 Interfering substances

4.4.2.4.1 The experimental conditions of tests intended to demonstrate the microbicidal activity of the disinfectant *in vitro* shall consider the conditions of use of the disinfectant, which should include

the effect on microbial efficacy of re-use, and if applicable the absence of rinsing between cleaning and disinfection.

NOTE 1 National regulatory authorities can require rinsing between cleaning and disinfection.

NOTE 2 [EN 14885](#) provides examples of test conditions.

4.4.2.4.2 The efficacy of the disinfectant and the interaction between the disinfectant and residues (e.g. soil, detergents) shall be tested under conditions in which residues are at or above the maximum level that might occur in use and the disinfectant is at or below the minimum specified in-use concentration.

4.4.2.5 When tested in accordance with [6.12.6](#) for the minimum exposure time at the MRC and the minimum temperature to be used in the WD, the disinfection stage shall demonstrate:

— at least 6 log₁₀ inactivation of the most resistant *Mycobacterium* sp. to the disinfectant.

Variations in volume of water and disinfectant shall be considered.

NOTE National regulatory authorities can require testing on additional strains, and different inactivation values.

4.4.3 Temperature

The temperature of the disinfecting agent 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 appropriate, by operating the WD at ambient temperature with means to prevent operation of the WD when the disinfectant temperature is outside the specified temperature range.

4.4.4 Process monitoring

The process monitoring of each operating cycle by the automatic controller shall include verification that the process conditions specified by the WD manufacturer as necessary and sufficient for disinfection to take place (e.g. disinfectant concentration, temperature and contact time) were attained (see also [5.5](#)).

Microbial testing (e.g. with biological indicators or inoculated carriers) of the disinfection stage on each cycle shall not be used to meet this requirement.

NOTE Confirmation of the concentration of disinfectant can require, for example, 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. (see also [4.4.5.2](#)).

4.4.5 Disinfectant use

4.4.5.1 General

The disinfectant(s) to be used shall be specified, as established during type testing. Additional disinfectants may be used if established by further type testing [see [8 n](#)].

Disinfectant solutions shall either be discharged after a single use during each cycle or re-used for a limited number of cycles (see [4.4.5.2](#)). Discharge after a single use, during each cycle, is the preferred option.

4.4.5.2 Re-use of disinfectant solutions

If the WD is designed to allow the same disinfectant solution to be used on two or more consecutive operating cycles then steps shall be taken to ensure that the activity and safety (e.g. accumulation of foreign material, device compatibility) of the disinfectant solution are not impaired during its working life.

This shall include the following:

- a) Means shall be specified to ensure that the disinfectant solution has retained the required antimicrobial activity. 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, to be monitored to indicate the antimicrobial activity of the disinfectant. Suitable parameters include e.g. pH, stability, concentration of the active ingredient, and adjuvants that could also affect performance.

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

- b) The maximum period or number of operating cycles for which the disinfectant may be used shall be recommended to the user. 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 operate an audible and visible alarm and prevent the use of the operating cycle until chemicals are changed.

It shall be recommended that the user monitors the disinfectant concentration using the method provided by the disinfectant manufacturer, e.g. an indicator test strip, specific for the disinfectant to show that the disinfectant is at or above the MRC (see also [4.4.4](#)). It shall be recommended that the user replaces the disinfectant solution with fresh solution when it reaches its maximum number reuse days/maximum number of operating cycles or the MRC, whichever comes first [see [4.4.5.2 c](#)].

4.5 Final rinsing

4.5.1 The chemical purity of the final rinse water in contact with the load shall be specified.

When the water for the final rinse is disinfected by adding a chemical disinfectant to the water, it shall be demonstrated that residues of this disinfectant will not cause any harm to the user or the patient.

4.5.2 The final rinse water shall meet the requirements for microbiological quality as given in [4.9.2.3](#).

4.5.3 Depending upon the intended site of use of the endoscope (e.g. sterile body site) the level of bacterial endotoxins in the final rinse water shall be controlled and monitored within the limits specified in national regulations, using the method described in ISO 15883-1:2006+Amd 1:2014, 6.4.2.3.

NOTE It is the dose of endotoxin that ultimately impacts on the patient and this includes the exposure surface area of an endoscope as well as the endotoxin concentration in the final rinse water.

4.5.4 On completion of the final rinse stage the water shall not be stored for subsequent re-use in the rinsing stage of subsequent cycles.

4.6 Purging to remove rinse water

4.6.1 The WD shall include a means of purging rinse water from the channels of the endoscope(s) at the end of the final rinse stage.

4.6.2 Whenever the channels of the device are purged with air, the air shall be oil free and shall be filtered through a filter, Class H13 or higher as specified in [EN 1822-1:2009](#) (see ISO 15883-1:2006+Amd 1:2014,4.5.4).

NOTE This HEPA filter provides not less than 99,99 % arrestance to particles of 0,2 µm and larger.

4.7 Drying

4.7.1 Where the WD has no drying stage or has a user selectable drying stage, the instructions for use shall indicate that the device and the channels of the device shall be dried prior to storage in accordance with [8 k\)](#), 2).

NOTE 1 Automatic cycles in which the device is not dried are intended for use on devices which will be used without storage.

NOTE 2 Purging with 0,2 µm filtered alcohol (e.g. 70 % isopropanol) can be used to aid drying, if compatible with the medical device.

4.7.2 The quality of air used during the drying stage shall be at least that defined in [4.6.2](#).

4.7.3 When tested in accordance with [6.8](#) there shall be no visible droplets of moisture.

4.8 Self-disinfection

4.8.1 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+Amd 1:2014, 5.3.1.2).

NOTE 1 The self-disinfection process is intended also to deal with the situation where the WD has become contaminated. The piping used to convey rinse water to the endoscope, if contaminated, can easily develop a layer of biofilm containing many microorganisms in a state in which they are highly resistant to chemical disinfection.

NOTE 2 Thermal disinfection using moist heat is the preferred method. The temperature used can be higher than the normal maximum operating temperature available for the loaded WD.

When chemical self-disinfection is used a disinfectant containing a disinfecting agent different from that used for disinfecting the endoscope or the same disinfectant under different conditions (e.g. formulation, increased temperature, higher concentration, extended contact time etc.) shall be used.

NOTE 3 The use of the same disinfecting agent used under the same conditions can carry the risk of allowing organisms resistant to that particular disinfectant to proliferate.

4.8.2 A WD in which the endoscope process cycle provides for disinfection of the chamber and all piping and tanks which come into contact with the water or solutions used for cleaning, disinfecting and rinsing the load shall be deemed to meet this requirement (see [4.8.1](#)) without the provision of an additional self-disinfection cycle. The standard cycles shall then be subject to the same test as the self-disinfection cycle (see [6.12.5](#)).

4.8.3 Details of the parts of the WD subjected to the self-disinfection cycle and whether this cycle includes the water treatment equipment shall be provided [see [4.9](#) and [8 h\)](#)].

4.8.4 When different from the normal operating cycle 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 up to the air break;

- d) include means to warn the user that the WD shall be operated without any load in the chamber and, so far as practicable, include means to verify that no device is present before the cycle will operate;
- 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 600.

4.8.5 The self-disinfection cycle shall ensure that a WD that has become contaminated through failure of the water treatment equipment can be effectively disinfected. Compliance shall be verified by testing in accordance with [6.12.5](#). After carrying out a self-disinfection cycle, the performance shall be deemed to be satisfactory if the final microbial count is 10 CFU/100 ml or fewer, and free from *Pseudomonas aeruginosa* in 100 ml, and if required for operational and routine testing, the sample is free from (atypical) *Mycobacterium* sp. in 100 ml (see [6.12.5](#)).

NOTE Methods for microbiological evaluation of disinfection of the liquid transport system are specified in [Annex D](#).

4.8.6 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 [see [8 l](#)].

4.8.7 For chemical disinfection systems a microbiological test shall be required. The test shall be designed to ensure that the self-disinfection cycle will disinfect contaminated tubing by evaluating the effect of the cycle against a biofilm containing *Pseudomonas aeruginosa* (see ISO/TS 15883-5:2005, Annex F). The capability of the WD to provide self-disinfection shall be deemed to have been established if, when tested in accordance with [6.12.3](#), the required microbial reduction factor has been achieved.

4.8.8 National regulatory requirements can specify approval procedures for validating self-disinfection of WD for medical devices. Compliance with these national requirements shall be deemed to meet the requirements of [4.8](#) within the territory where these requirements apply.

4.9 Water treatment equipment

4.9.1 General

The water treatment equipment (softeners, de-ionizers, filters etc.) shall be operated within the specified limits (e.g. flow rates, supply pressures).

NOTE See ISO 15883-1:2006+Amd 1:2014, 5.23.

4.9.2 Disinfection of water treatment equipment

4.9.2.1 When the water treatment equipment is a part of the WD, the former shall be designed and constructed so that it can be periodically submitted to a disinfection procedure. Guidance on the minimum frequency with which the equipment shall be disinfected shall be stated according to the information supplied by the purchaser for the quality of the water supply and the manufacturer of the water treatment equipment [see [8 i](#)].

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

The actual frequency shall be specified based on, 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 treatment equipment disinfection procedure to provide self-disinfection shall be deemed to have been established when tested in accordance with the methods given in 6.12.4 and 6.12.5. There shall be less than 10 CFU recovered from each of the two 100 ml samples and other controlling parameters shall be achieved.

4.9.2.2 If the water treatment equipment is not part of the WD, then 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 4.3.4 and 8 p)].

NOTE To meet the specification of the permissible microbial contamination of the water supply, it can be necessary to make provision for maintenance of the external water treatment equipment (e.g. filter replacement, disinfection, ultraviolet sources, calibration of dosing system).

4.9.2.3 Means shall be provided to disinfect incoming water used for the final rinse. The disinfection process shall ensure that:

- a) there are less than 10 CFU/100 ml sample of final rinse water when tested in accordance with E.3.2; and
- b) the water is free from *Pseudomonas aeruginosa* in 100 ml, and (atypical) *Mycobacterium* sp. in 100 ml when tested in accordance with E.3.3 (see 6.3).

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

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

4.9.2.4 The connection between the water supply, which has been treated to remove microbial contamination, and the circulation system for rinsing the endoscope, shall be designed and constructed to prevent recontamination of the water.

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 [see 8 h) and 8 i)].

4.9.2.5 If the water treatment equipment is part of the WD, then where possible, the final rinse water treatment used to fulfil the requirements of 4.5 shall be monitored by the WD automatic controller to verify that the parameters affecting the efficacy of the water treatment equipment remain within specification. If the monitoring cannot be done by the automatic controller, then all the parameters to be verified during validation and routine monitoring shall be specified [see 8 s)].

4.9.3 Maintenance of piping

The planned preventive maintenance required on the piping that is part of the WD and is used to convey final rinse water to the endoscope shall be specified. This shall include the frequency at which such piping should be replaced [see 8 m)].

5 Mechanical and process requirements

5.1 Materials – Design, manufacture and construction

5.1.1 The maximum temperature of any process fluid in contact with the load shall be controlled below the temperature that would cause degradation of the device(s) which the WD is intended to process (see ISO 15883-1:2006+Amd 1:2014, 4.1.4).

5.1.2 The load carrier intended to accommodate the device(s) to be processed shall be designed and constructed to minimize the possibility of damage to the device(s) at the time of loading, during processing and during the course of unloading.

5.2 Device channel irrigation system

5.2.1 General

5.2.1.1 The connectors for each of endoscopes that the WD is designed to process shall be provided [see 8 a) and 8 b)]. The connectors shall be of the same design as the connectors used in the type testing of the WD.

NOTE 1 Connectors from a source other than the WD manufacturer might not be of the same design as the connectors used in the type test. The type test results might therefore not be valid when these third party connectors are used, and this can result in an inadequately processed endoscope.

During at least part of each of the cleaning, disinfection and rinsing stages, the device channel irrigation system shall ensure that the various process fluids flow through each of the internal channels and/or cavities of the devices that are required to be cleaned and disinfected. Assurance that this has taken place shall be provided either by:

a) the automatic controller providing means to verify the flow of process fluids through each channel (see 5.2.2);

or

b) requiring in the instructions for use that the user:

- 1) verifies that all channels allow the free passage of process fluids before the device is loaded into the WD;
- 2) confirms that all necessary connections were made before, and were still in place at the end of the cycle;
- 3) confirms by reference to the WD process record that the supply of process fluids was maintained during each stage of the process (see 5.6);
- 4) verifies flow through each endoscope channel at the end of each operational cycle or immediately before use.

For some endoscopes the automatic flow verification system might not work properly due to technical limitations. Those endoscope lumens and devices shall be clearly identified [see 8 a)] and prescribed that for these particular endoscopes the user reverts to method b) to verify the irrigation of the channels.

NOTE 2 Option a) above is the preferred method. Option b) will burden the user with additional requirements for staff training, and staff resources needed to perform these additional steps in processing. Further, it will likely increase the incidence of user error and will degrade the quality and completeness of independent documentation that the process was completed correctly.

5.2.1.2 A diagram shall be provided of the circulation pathway of the fluids for all channels of each medical device that the WD is intended to process (see [4.1.2](#)) based on information from the manufacturer of each device [see [8 j](#)].

Where an endoscope is part of an existing endoscope type test group, it shall be sufficient to provide a flow diagram for that endoscope type test group (see [Annex H](#)).

The flow diagram and/or instructions shall show any limitations on how, or to which endoscope port on the WD, the endoscope channels shall be connected [see [8 r](#)].

5.2.1.3 Minimum and maximum flow and maximum pressure that the WD is designed to deliver to each channel or channel system shall be specified. If the WD is intended to process a specific medical device then the specified maximum pressure(s) and flow(s) shall not be exceeded [see [8 d](#)].

In cases where different channels are irrigated at different pressures, the connection systems shall be designed to prevent incorrect connections.

5.2.2 Verification of device channel irrigation by the automatic controller

5.2.2.1 The maximum extent of flow reduction permissible (e.g. change in flow volumes, pressures, rates) that will not impair the efficacy of the process for each channel or channel systems shall be specified [see [8 e](#)].

To enable determination of the flow that will occur through the unobstructed channels of the medical device, relevant data shall be obtained, e.g. dimensions of connectors, internal dimensions of channels, and maximum pressures to which channels may be subjected.

When one or more channels of the device are obstructed to an extent that would impair the efficacy of the process, the automatic controller shall cause a fault to be indicated.

Compliance with this requirement shall be demonstrated by testing in accordance with [6.6](#).

NOTE With some designs of endoscope a blockage in one channel could cause the flow to be diverted to another channel or endoscope port. Under these circumstances detection of an obstruction by the automatic controller might not be reliable. The user might need to refer to the device manufacturer's instructions for the method to be used to verify that all channels are free from obstructions.

5.2.2.2 When one or more channels of the device are not connected to the WD, the automatic controller shall cause a fault to be indicated.

Compliance with this requirement shall be demonstrated by testing in accordance with [6.7](#).

5.2.2.3 The automatic controller shall verify that the duration of flow of the relevant process fluids met or exceeded the minimum exposure times established during type testing as necessary for each process stage. Failure to achieve the required flow shall cause a fault to be indicated.

5.2.2.4 When there is a common connection for fluid at the same supply pressure to more than one channel, evidence shall be provided that the flow through each of the channels meets, or exceeds, the minimum required for effective cleaning, disinfection and rinsing of each device channel to be processed.

5.3 Venting and drainage systems

The WD shall be designed and constructed to ensure that there is no noxious discharge as specified in [IEC 61010-2-040](#).

NOTE Attention is drawn to local regulations concerning the concentration of process chemicals discharged to waste and the temperature of drain effluent.