International Standard

ISO 15883-2

Second edition
2024-11

Washer-disinfectors —

Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

Laveurs désinfecteurs —

Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des dispositifs médicaux critiques et semi-critiques

Reference number
ISO 15883-2:2024(en)

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Published in Switzerland

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Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-2:2006), which has been technically revised.

The main changes are as follows:

— change of title to reflect application to critical and semi-critical medical devices;

— addition of new terms defining critical and semi-critical medical devices, and non-critical devices;

— alignment of other terms and definitions with ISO 11139:2018+Amd 1:2024;

— revision of cross-references to relevant clauses in ISO 15883-1:2024 and ISO 15883-5:2021;

— the upper limit of the washing temperature band reduced to +5 °C;

— addition of a clause on water quality (see 4.5);

— clarification of requirements for lumen and powered devices (see 5.1);

— addition of informative Annex B providing guidance on assigning a medical device to a product family for cleaning and thermal disinfection processes;

— revision of references in the Bibliography.

A list of all 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 document is the second part of the ISO 15883 series of standards specifying the performance of washer-disinfectors (WD) and the general requirements for performance applicable to instrument WD. The requirements given in this document apply to WD used for cleaning and thermal disinfection of critical and semi-critical medical devices intended for reuse such as:

— surgical instruments, which are divided into instrument product families based on design features, e.g. instruments without hinges, cavities or lumens, with hinges, with sliding shafts, with lumens, microsurgical instruments, and complex instruments (e.g. robotic);

— powered instruments;

— anaesthetic and respiratory equipment;

— medical devices comprising glass components;

— any non-critical devices used in conjunction with critical and semi-critical medical devices.

Requirements for WD for other applications, such as for processing non-critical devices and thermolabile endoscopes, are specified in other parts of the ISO 15883 series of standards.

When processed in the WD, the medical devices can be intended for immediate use or can be intended for further processing. In both cases, the efficacy of the cleaning and disinfection is of major importance. In either case, this is for the well-being of the patient. In the latter case, it is also for the safety of the staff who handles the instruments in the process of inspection, testing and packing as well as ensuring that the sterilization process is not challenged by residual soil.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. Users should be aware that some medical devices can require pre-treatment, e.g. soaking, brushing, ultrasonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical device instructions for reprocessing (see also the ISO 17664 series).

Safety requirements for WD are given in IEC 61010-2-040.

NOTE Local or national regulations can apply in respect of the potential adverse effects on the quality of water intended for human consumption or environmental impacts caused by the WD and its intended use.

Washer-disinfectors —

Part 2:
Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

1 Scope

This document specifies requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of reusable critical and semi-critical medical devices, such as surgical instruments, anaesthetic equipment, and any non-critical devices used in conjunction with critical and semi-critical medical devices, such as bowls, dishes and receivers, utensils and glassware.

This document is intended to be used in conjunction with the general requirements specified in ISO 15883-1:2024, except those specified in 4.1.1.

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

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 4017, *Fasteners — Hexagon head screws — Product grades A and B*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 5362, *Anaesthetic and respiratory equipment — Anaesthetic reservoir bags*

ISO 5367, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 15883-1:2024, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO 15883-5:2021, *Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1:2024 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
access device
means by which entry to restricted parts of equipment is achieved

Note 1 to entry: This can be by dedicated key, code or tool.

[SOURCE: ISO 11139:2018, 3.4]

3.2
critical medical device
<washer-disinfector> item processed in a washer-disinfector, intended to be introduced directly into, or have contact with, the vascular system or normally sterile areas of the body

EXAMPLE Surgical instruments.

Note 1 to entry: Critical medical devices usually require sterilization before use.

Note 2 to entry: National regulations can use alternative wording for this term.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.333]

3.3
non-critical device
<washer-disinfector> item processed in a washer-disinfector, whose surface(s) are intended to contact intact skin of a body but do not penetrate it, or device not intended for direct patient contact

EXAMPLE Blood pressure cuffs, wheelchairs, trays, bowls, dishes, glassware, receivers, containers for transit.

Note 1 to entry: National regulations can use alternative wording for the definition of this term when applied to medical devices.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.357]

3.4
powered device
<washer-disinfector> surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

Note 1 to entry: The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle, or belt) or by the flow of a pressurized fluid or compressed air.

EXAMPLE Dental hand pieces, orthopaedic saws, and drills.

[SOURCE: ISO 11139:2018, 3.199]

3.5
product family
group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes

Note 1 to entry: Design characteristics present specific challenges during the washing stage of medical devices in a washer-disinfector.

[SOURCE: ISO 11139:2018, 3.218, modified — Note 1 to entry added.]

3.6
semi-critical medical device
<washer-disinfector> item processed in a washer-disinfector, that, during use, contacts mucous membranes or non-intact skin of a body

EXAMPLE Some probes, some respiratory therapy equipment.

Note 1 to entry: National regulations can use alternative wording for this term.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.369]

3.7
washing temperature
minimum temperature of the washing temperature band

[SOURCE: ISO 11139:2018, 3.322]

3.8
washing time
period for which the cycle variables are maintained within the values specified for washing

EXAMPLE Temperature of the load, detergent concentration in the chamber.

[SOURCE: ISO 11139:2018, 3.323, modified — Example added.]

3.9
worst-case
set of conditions, as compared with ideal conditions, justified to pose the highest probability of process or product failure

Note 1 to entry: The set of conditions do not necessarily induce product or process failure.

Note 2 to entry: The set of conditions should be specified within the limitations of the intended use.

Note 3 to entry: The set of conditions should encompass upper and lower processing limits and circumstances.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.376]

4 Performance requirements

4.1 General

4.1.1 The requirements of ISO 15883-1:2024 apply with the exception of:

— ISO 15883-1:2024, 4.3.2 (which refers to chemical disinfection);

— ISO 15883-1:2024, 5.7.5 (which refers to the accuracy of dosing systems; see 4.1.6).

4.1.2 The WD shall be designed to clean and thermally disinfect specified medical devices that are intended to be reused and are designated as compatible with the WD process cycle [see ISO 15883-1:2024, 8.1 b) 2)]. Processing of medical devices in the WD shall be in accordance with the intended use of the WD and the instructions for processing the device as specified in accordance with ISO 17664-1:2021, Clause 6.

NOTE Some process chemicals or heat can promote fixation of proteinaceous or other soils to the devices to be cleaned and can therefore interfere with the removal of soil.

4.1.3 The medical devices shall be cleaned and disinfected on the outer surfaces, including covered surfaces and crevices, and where necessary for their safe use, safe handling and correct functioning, the inner surfaces. Any necessary dismantling for processing the inner surfaces shall be conducted as specified in accordance with ISO 17664-1:2021, 6.5.

4.1.4 If necessary for the process success or safety of load items, the WD shall be provided with means to facilitate the correct alignment of the load and load carrier(s) in the WD chamber.

4.1.5 In order to process lumen devices or powered devices, the WD shall be provided with the load carrier(s) and necessary connectors that shall be designed to ensure adequate irrigation with process fluids through each device.

4.1.6 The volume of the process chemical(s) that is/are admitted (see ISO 15883-1:2024, 5.7.2, 5.7.4 and 5.7.6) shall be adjustable by means of an access device that shall deliver the set volume to an accuracy of ± 5 % or better.

NOTE The volume of water admitted to the WD chamber can affect the effective concentration of process chemicals.

4.1.7 During any stage of the operating cycle, the process conditions affecting irrigation inside the pipework system shall be maintained above a specified level that is required for an effective cleaning, disinfection and rinsing process for any load configurations [e.g. load, load carrier(s), and if applicable, inside the pipework for connectors].

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1:2024, 4.2 and the performance requirements and test method criteria specified in ISO 15883-5:2021, Clause 4.

The cleaning process shall also meet the requirements of the test specified in 6.2.

Where applicable, any treatment required prior to cleaning in the WD shall be performed in accordance with the instructions for use for the load in ISO 17664-1:2021, 6.4 and 6.5, or for WD in ISO 15883-1:2024, 8.1 a).

4.2.2 During the washing stage the following applies:

— the washing time shall start when the temperature at the control sensor of the WD reaches the lower limit of the first specified washing temperature band;

— the temperatures recorded on the surface of the load and load carrier(s) for the washing stage follow the temperature profile defined for this stage and are within +5 °C of the relevant set temperature for each holding time of the stage.

NOTE A washing stage can include two or more washing temperatures.

4.3 Disinfecting

4.3.1 Each operating cycle shall include a thermal disinfection stage for which the time at which the load is maintained at the disinfection temperature gives an A_0 of at least 600 on all surfaces of the load and load carrier(s) to be disinfected when tested in accordance with 6.3.

NOTE 1 See Kremer et al.[13].

NOTE 2 Thermal disinfection can be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

The chosen locations of the sensors for thermometric testing shall be appropriate to the load and shall be justified.

4.3.2 The operating cycle shall include a thermal disinfection stage giving an A_0 of at least 600 on all the inner surface of the chamber when tested in accordance with 6.3 and ISO 15883-1:2024, 6.8.3.

4.3.3 The WD shall be capable of being set for disinfection stages that deliver an A_0 of at least 3 000.

NOTE Regional or national regulations can apply.

4.3.4 If the disinfection is done with steam, the temperature on the surfaces of the load, chamber walls, drain or the free chamber space shall remain below the boiling point of water corresponding to the pressure in the WD chamber in order for the water to remain on the surface of the device to be disinfected.

Conformity to this document shall be verified by examination of the data obtained from thermometric testing (see 6.3).

4.4 Temperature of inner surfaces of processed devices

For anaesthetic and respiratory tubing, lumen devices and powered devices, the temperature requirements for the inner surfaces shall be deemed to have been achieved when:

— the temperature of the process fluids at the connection to the devices and the discharge from the devices is within the limits specified for the WD and conforms to 4.2 and 4.3;

— the flow of the process fluids at the connection to the medical device is within the limits specified when tested in accordance with 5.1.2 and 6.3.3.

4.5 Water quality

The quality of water required for each processing stage shall be specified. The choice of water quality shall ensure appropriate processing of the medical devices suitable for their specified intended use.

For specific application, or for optimizing the process, specific grades of purified water are recommended depending on the resulting risk.

NOTE 1 See ISO 15883-1:2024, ISO/TS 5111 and ANSI/AAMI ST 108.

NOTE 2 Regional or national regulations or guidelines can apply.

5 Mechanical and control requirements

5.1 Lumen and powered devices

5.1.1 Irrigation

5.1.1.1 For lumen devices and powered devices in which the inner surfaces are to be flushed, means shall be provided to irrigate the medical device. Risk assessment shall be used to define critical performance and usability parameters of the process. The effectiveness of the cleaning and disinfection process employing the required means shall be demonstrated.

NOTE Performance and usability parameters can include, e.g. damage of the device, wear, connection error, pull-off force, disconnection.

5.1.1.2 For powered devices, when required in accordance with validated device processing methods, means shall be provided to drive the instrument during the operating cycle to ensure that all the inner surfaces of, for example, axles and gears, come into contact with the process fluids for the specified times without causing damage to the devices.

5.1.1.3 Validated means of connection shall be specified (see Clause 8) to conform with the requirements of this document.

5.1.2 Verification of flow through lumen and powered devices

5.1.2.1 During the cleaning, disinfection and rinsing stages, it is necessary for the various process fluids to flow through each of the internal channels 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) requiring in the instructions for use that the user:

   1) verifies that all channels allow the free passage of fluids before the device is loaded into the WD;

      NOTE 1 Some devices can include channels that require a particular method for verifying that the channel is unobstructed.

   2) confirms that all necessary connections were made before, and were still in place at the end of the operating cycle;

   3) verifies that the process verification record confirms the attainment of washing pressure or flow (see 4.1.7);

      NOTE 2 Nozzles and narrow lumen devices can be protected from blockage as defined in ISO 15883-1:2024, 5.6.2.

   or

b) the automatic controller providing means to verify the flow of process fluids through each channel. Failure to achieve the specified flow through each channel shall cause a fault to be indicated.

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

5.2 Control systems

5.2.1 Means shall be provided to pre-set the washing temperature and time over specified ranges appropriate for the process chemical(s) [see ISO 15883-1:2024, 8.1 b) 4)]. Adjustment shall be by means of an access device.

5.2.2 Means shall be provided to pre-set the minimum disinfection temperature to be no lower than 70 °C and up to the maximum temperature specified. Adjustment shall be by means of an access device.

5.2.3 Means shall be provided to pre-set the disinfection time. Adjustment shall be by means of an access device.

5.3 Process verification

The WD shall be equipped with a recording system with sensors and signal processing independent from the control system [see ISO 15883-1:2024, 5.11.4 b)] for inclusion of temperature and pressure or flow as a minimum.

6 Testing for conformity

6.1 General

Testing for conformity shall be carried out in accordance with ISO 15883-1:2024, Clause 6.

NOTE 1 Annex A includes a summary of test programmes for WD, e.g. surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils, glassware, in addition to those recommended in ISO 15883-1:2024, Annex A.

Cleaning tests shall be performed on each product family intended to be processed in the WD [see ISO 15883-1:2024, 8.1 b) 2)].

NOTE 2 The load can be grouped into product families (see Annex B for guidance).

6.2 Tests for soil removal from chamber walls, load carrier(s) and load

The tests shall be carried out in accordance with ISO 15883-1:2024, 6.10 using the performance requirements and test method criteria in accordance with ISO 15883-5:2021.

NOTE Regional or national requirements can require the use of particular test soils and methods.

WD manufacturers should be aware of the user's choice of test soil(s) and method(s) for operational qualification testing; this can indicate a need to carry out similar testing before the WD is supplied.

The use of test soils for the load, chamber walls and load carrier(s) may be different. Where different test soils are used, the rationale for the choice of test soil shall be documented.

6.3 Thermometric tests

6.3.1 General

The tests shall be performed in accordance with ISO 15883-1:2024, 6.8, with the modifications given in 6.3.2 to 6.3.3.

6.3.2 Temperature of outer surfaces of devices

6.3.2.1 General

The load temperature test shall be carried out in accordance with the requirements of ISO 15883-1:2024, 6.8.2. The test loads specified below are reference loads which shall be used for type tests and may be used for the works test or operational qualification. A full load of medical devices of the type to be processed, or surrogates for these devices, may be used for operational qualification testing but recourse to the reference loads given below shall be made in case of dispute.

6.3.2.2 Solid devices

For operational qualification testing of solid devices (e.g. most surgical instruments), the test load shall consist of a mass of stainless-steel bolts evenly distributed throughout the loading space to the maximum mass of load specified for the WD. The bolts shall be:

— in conformity with ISO 4017;

— austenitic stainless-steel grade conforming to EN 10088-2;

— M12 × 100 mm with hexagon heads;

— cleaned, degreased, and dried before use.

For performance qualification testing, a full load of instruments of the type intended to be processed shall be used.

6.3.2.3 Bowls, dishes, and receivers (including both polypropylene and metal)

The test load shall consist of a specified maximum load and shall include all or part of the list of the following items depending on the size of the chamber and the intended use of the WD:

— one instrument tray 200 mm × 150 mm;

— one instrument tray 300 mm × 250 mm;

— one kidney dish 150 mm × 350 mm;

— one lotion bowl of 100 mm × 45 mm;

— one lotion bowl of 250 mm × 110 mm;

— one gallipot of 40 mm diameter (30 ml to 60 ml);

— one gallipot of 80 mm diameter (250 ml to 280 ml).

When the WD is to be used to process reusable instrument containers (see EN 868-8) the load items specified above shall be replaced with a 300 mm × 600 mm × 150 mm container and internal basket and a 300 mm × 300 mm × 150 mm container and internal basket.

6.3.2.4 Glassware

The test load shall consist of a specified maximum and shall include all or part of the list of the following items depending on the size of the chamber and the intended use of the WD:

— 100 rimless test tubes with an outside diameter of 16 mm, a length of 100 mm and wall thickness of 1,2 mm;

— 24 low-form beakers, with spout, and a volume of 1 000 ml, diameter of 106 mm and a height of 145 mm.

6.3.3 Temperature of inner surfaces of devices

6.3.3.1 General

For inner surfaces of devices, the following additional test requirements apply:

a) Insert one (1) temperature sensor in each connector or in the pipe to the connector, as close to the connector as possible (it can be necessary to modify the connector or the pipe to the connector in order to position the temperature sensor).

b) Insert a temperature sensor in the discharge of process fluid from the device. The temperature sensor shall be shielded from heating by contact with process fluids within the chamber.

For operational qualification and performance qualification testing, the four (4) points identified during type testing as representing the range of temperatures shall be used (see ISO 15883-1:2024).

6.3.3.2 Anaesthetic and respiratory accessories

The WD shall be fully loaded and include all of the items from the following list:

— one (1) breathing tube conforming to ISO 5367;

— one (1) anaesthetic reservoir bag with 15 mm connector, 1,5 l capacity conforming to ISO 5362;

— one (1) anaesthetic reservoir bag with 22 mm connector, 1,5 l capacity conforming to ISO 5362;

— two (2) unassembled conical connectors for anaesthetic and respiratory equipment, of 15 mm, screw threaded, and with cone and socket joints conforming to ISO 5356-2;

— two (2) unassembled conical connectors for anaesthetic and respiratory equipment, of 30 mm, screw-threaded, and with cone and socket joints conforming to ISO 5356-2;

— a tracheostomy tube and connector, conforming to ISO 5361 of 11 mm or of a larger size if the WD is intended to process a larger size;

— an endotracheal tube connector, conforming to ISO 5361 of 11 mm or of a larger size if the WD is intended to process a larger size;

— four (4) face masks.

Where the volume of the chamber exceeds the total volume of the listed items, then the remaining volume shall be filled with additional anaesthetic and respiratory accessories.

Where the volume of the chamber is insufficient to accommodate every item from this list, then selected items may be chosen.

6.3.3.3 Lumen devices

The usable space shall be filled to the maximum capacity with the lumen devices which the WD is designed to process, as specified by the manufacturer of the WD. This test load shall be evenly distributed throughout the usable space with the specified load support system in place.

6.3.3.4 Powered devices

The usable space shall be filled to the maximum capacity with the powered devices for which the WD is designed to process, as specified by the manufacturer of the WD.

6.4 Pressure and flow measurement

A test method shall be specified to measure pressure or flow, within or supplied to lumen devices.

7 Information to be provided for the WD

In addition to the information listed in ISO 15883-1:2024, Clause 8, the purchaser shall be provided with the following information:

a) range of load carrier(s) available and required;

b) range of connectors that are available and required for the processing of lumen devices, hollow instruments or powered devices;

c) the following information obtained by testing in accordance with 6.3:

   1) the time for an operating cycle;

      NOTE The voltage supply, temperature of tap water and the loading mass can influence this time period.

   2) the locations and temperatures of the coolest and hottest parts inside the chamber of the WD;

d) the minimum pressure level inside the pipework system at the connectors, i.e. to provide the flow through hollow and lumen devices;

e) the test method to measure pressure or flow (see 4.1.7 and 5.1.2);

f) means of connection of lumen and powered devices (see 5.1.1.3).

8 Information to be requested from the purchaser by the supplier of the WD

In addition to the information listed in ISO 15883-1:2024, Clause 10, the following information shall be requested from the purchaser by the supplier of the WD:

a) whether load carrier(s) for bowls, dishes and receivers and connectors for either hollow devices or powered devices, or both, need to be installed and in what numbers and locations;

b) the combination of time and temperature or A_0 value to be attained for thermal disinfection (see 4.3.2).

Annex A
(informative)

Summary of test programmes

Table A.1 summarizes the recommended test programmes applicable to WD for thermal disinfection of critical and semi-critical medical devices, in addition to those recommended in ISO 15883-1:2024, Annex A. Other tests or schedules of tests providing equivalent assurance are equally acceptable.

Table A.1 — Summary of test programmes for WD for thermal disinfection of critical and semi-critical medical devices

Brief description of test	Requirements clause	Test clause	Type test	Works test	Operational qualification	Performance qualification	Routine test
Temperature of inner and outer surfaces of devices	4.3.1 4.4	6.3.2 6.3.3	X	X	X	X	B
Verification of pressure or flow for lumen devices	4.1.7	6.4	X	B	B	X	B
Key X = recommended B = not recommended							

Annex B
(informative)

Guidance on the designation of a medical device to a product family for cleaning and thermal disinfection processes

B.1 General

The purpose of this Annex is to determine the efficiency of a WD on a product family that represents a comparable challenge to the WD. To facilitate the type tests required for the cleaning performance and thermometric tests for the load (see Clause 6), the compatible load can be divided into product families and the tests conducted on the representative worst-case device in the family. This approach can limit the number of tests necessary and can still ensure that different characteristics that can influence the reprocessing result are taken into account during type testing.

This annex provides guidance, based on existing classifications in published literature, as well as points to consider on how to classify compatible load items into product families. Each medical device intended for processing should be classified using selected design attributes.

This guidance is based on similar guidance published in ISO/TS 17665-3[1)], ISO 15883-4, ISO 17664-1, and Reference [10].

B.2 Design attributes

The design of the medical device influences the access of the process fluid to contact all external and, if present, internal surfaces and thus determines the cleaning efficacy and the achievement of a specified A_0 value necessary for successful processing. In addition, special equipment such as adapters or special load carriers can also be required to achieve sufficient washing of the surfaces or flushing channels or cavities.

Physical (geometric) design attributes can be taken into account when assigning a particular device to a product family for processing in a WD. These attributes can include, but are not restricted to, the following examples:

— cavities, including those needing adaptors;

— joints, cocks, taps, spigots, hinges, including those needing disassembling or opening of the device before processing;

— ports and port closures;

— WD connectors;

— internal non-return valves;

— ball gearings, gears;

— dead volumes;

— lumen devices: restriction of channels/internal connection between channels/length and diameter of channels;

— materials of coating/outer surfaces;

— dismantlable/non-dismantlable.

1) Withdrawn.