भारतीय मानक
Indian Standard

IS/ISO 15883-2 : 2006

धोनेवाले-कीटाणुशोधक

भाग 2 शल्य चिकित्सा उपकरण, एनेस्थेटिक उपकरण, कटोरे, बर्तन (डिश), रिसीवर, बर्तन, काँच के बने पदार्थ, आदि के लिए थर्मल कीटाणुशोधन इस्तेमाल करते हुए धोनेवाले-कीटाणुशोधक के लिए आवश्यकताएँ और परीक्षण

Washer-Disinfectors

Part 2 Requirements and Tests for Washer-Disinfectors Employing Thermal Disinfection for Surgical Instruments, Anaesthetic Equipment, Bowls, Dishes, Receivers, Utensils, Glassware, Etc

ICS 11.080.10

© BIS 2018

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली–110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

Nbsnadq2017

Price Group 5

Contents

Page

National Foreword ii
Introduction iv
1 Scope 1
2 Normative references 1
3 Terms and definitions 2
4 Performance requirements 2
4.1 General 2
4.2 Cleaning 3
4.3 Disinfecting 3
4.4 Temperature of internal surfaces of processed devices 4
5 Mechanical and control requirements 4
5.1 Load connectors 4
5.2 Control systems 5
5.3 Process verification 5
6 Testing for conformity 5
6.1 General 5
6.2 Tests for soil removal from chamber walls, load carrier and load 5
6.3 Thermometric tests 6
7 Information to be supplied by the manufacturer 8
8 Information to be requested from the purchaser by the supplier of the WD 8
Annex A (informative) **Summary of test programmes** 9
Bibliography 10

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

NATIONAL FOREWORD

This Indian Standard (Part 2) which is identical with ISO 15883-2 : 2006 'Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Hospital Equipment and Surgical Disposable Products Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard is published in six parts. Other parts of this standard are:

Part 1	General requirements, terms and definitions and tests
Part 3	Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
Part 4	Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
Part 5	Test soils and methods for demonstrating cleaning efficacy
Part 6	Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are,however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 4017 Hexagon head screws — Product grades A and B	IS 1364 (Part 2) : 2002 Hexagon head bolts, screws and nuts of product grades A and B : Part 2 Hexagon head screws (size range M 1.6 to M 64) (*fourth revision*)	Identical with ISO 4017 : 1999
ISO 5356-2 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors	IS/ISO 5356-2 : 2012 Anaesthetic and respiratory equipment — Conical connectors : Part 2 Screw-threaded weight-bearing connectors	Identical with ISO 5356-2 : 2012
ISO 5361 Anaesthetic and respiratory equipment — Tracheal tubes and connectors	IS/ISO 5361 : 1999 Anaesthetic and respiratory equipment — Tracheal tubes and connectors	Identical with ISO 5361 : 1999
ISO 5362 Anaesthetic reservoir bags	IS/ISO 5362 : 2006 Anaesthetic reservoir bags	Identical with ISO 5362 : 2006
ISO 5367 Breathing tubes intended for use with anaesthetic apparatus and ventilators	IS/ISO 5367 : 2000 Breathing tubes intended for use with anaesthetic apparatus and ventilators	Identical with ISO 5367 : 2000

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 15883-1 : 2006 Washer-disinfectors — Part 1: General requirements, definitions and tests	IS/ISO 15883-1 : 2006 Washer-disinfectors : Part 1 General requirements, terms and definitions and tests (*under print*)	Identical
ISO/TS 15883-5 : 2005 Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy	IS/ISO/TS 15883-5 : 2005 Washer-disinfectors : Part 5 Test soils and methods for demonstrating cleaning efficacy (*under print*)	do

The technical committee has reviewed the provisions of the following International Standards/Other Publications referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ISO 17664	Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN 10088-2	Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip for general purposes

The title of ISO 15883-1 : 2006 referred above may please be read as ‘Washer-disinfectors — Part 1: General requirements, terms and definitions and tests’.

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’.

Introduction

It is recommended that this Introduction be read in conjunction with the introduction to ISO 15883-1:2006.

This part of ISO 15883 is the second of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to instrument washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for cleaning and thermal disinfection of medical devices intended for re-use such as:

- surgical instruments;
- powered devices;
- instrument trays;
- instruments for minimally invasive surgery;
- lumen devices and tubing;
- rigid endoscopes;
- anaesthetic and respiratory equipment;
- bowls, dishes and receivers;
- glassware;
- containers for transit.

Fields of application within the scope of the ISO 15883 series of standards 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 the ISO 15883 series of standards.

When processed in the instrument washer-disinfector, the medical devices might be intended for immediate use or might be intended for packing and sterilization. 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 unduly 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 might require pre-treatment e.g. soaking, brushing, ultra sonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical manufacturer's instructions for reprocessing (see also ISO 17664).

Safety requirements for washer-disinfectors are given in IEC 61010-2-045.

Indian Standard

WASHER-DISINFECTORS

PART 2 REQUIREMENTS AND TESTS FOR WASHER-DISINFECTORS EMPLOYING THERMAL DISINFECTION FOR SURGICAL INSTRUMENTS, ANAESTHETIC EQUIPMENT, BOWLS, DISHES, RECEIVERS, UTENSILS, GLASSWARE, ETC

1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils and glassware.

NOTE 1 Thermal disinfection can be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

The requirements specified in this part of ISO 15883 are applicable in conjunction with the general requirements specified in ISO 15883-1.

The specified performance requirements of this part of ISO 15883 may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 2 If it is considered that prion protein can be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation.

2 Normative references

The following referenced documents are indispensable for the application 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, *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 reservoir bags*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

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

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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

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

3 Terms and definitions

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

3.1
A_0
equivalent time in seconds at 80 °C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K

[ISO 15883-1:2006, definition 3.1]

NOTE See also ISO 15883-1:2006, Annex B.

3.2
anaesthetic and respiratory accessories
respiratory tubes, anaesthetic reservoir bags and other anaesthetic products that will not be sufficiently flushed by rotating spray nozzles, but which require positioning over fixed spray/jet nozzles

3.3
lumen device
device that consists of tubes, pipes (either single or coaxial combined) which require connecting to the WD by means of dedicated connectors

3.4
powered device
surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

NOTE 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.

EXAMPLES Dental hand pieces, orthopaedic saws and drills.

3.5
washing temperature
minimum temperature of the washing temperature band

3.6
washing temperature band
range of temperatures, expressed as the washing temperature and the maximum allowable temperature which may prevail throughout the load during the washing time

3.7
washing time
period for which the cycle variables (e.g. temperature of the load, detergent concentration in the chamber) are maintained at or above the values specified for washing

4 Performance requirements

4.1 General

4.1.1 The requirements of ISO 15883-1:2006 apply with the exception of its

- subclause 4.3.2 (which refers to chemical disinfection, see Scope of this part of ISO 15883);
- subclause 5.7.5 (which refers to the accuracy of dosing systems; see 4.1.6 of this part of ISO 15883).

4.1.2 The WD shall be designed to clean and thermally disinfect specified medical devices that are intended by the device manufacturer to be reused and are designated as compatible with the WD process cycle in accordance with the device manufacturer's instructions for reprocessing as specified in accordance with ISO 17664.

4.1.3 The medical devices shall be cleaned and disinfected on the outer surfaces and where necessary for their safe use, safe handling and/or correct functioning, the inner surfaces.

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

4.1.5 In order to process lumen devices and/or powered devices, the WD shall be provided with the necessary connectors and load carriers which shall be designed to ensure an adequate flow of process fluids to each device.

4.1.6 The means to control the volume of the process chemical(s) that is/are admitted (see ISO 15883-1:2006, 5.7.2, 5.7.4 and 5.7.5) shall be adjustable by means of a key, code or tool and shall deliver the set volume to an accuracy of ± 5 % or better.

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1:2006 using the test soils and methods specified in ISO/TS 15883-5 that are pertinent to the loads to be processed.

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

4.2.2 During the washing stage:

- the washing time shall start when the temperature at the control sensor of the WD reaches the specified washing temperature;
- the washing temperature band shall have the lower limit defined by the washing temperature and an upper limit of, the washing temperature +10 °C (see ISO 15883-1:2006, 4.2.3).

4.2.3 Throughout the washing time the temperatures on any surface of the load, chamber walls, chamber drain and the load carrier shall:

- be within the washing temperature band;
- not differ from one another by more than 5 K.

NOTE A washing stage can include two or more washing temperatures and washing temperature bands.

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 to be disinfected when tested in accordance with 6.3.

4.3.2 The cycle shall include a thermal disinfection stage giving an A_0 of at least 600 on all the internal surfaces of the chamber and on the load carrier when tested in accordance with 6.3.

4.3.3 The WD shall provide for disinfection times and temperatures to be set to give an A_0 value up to a maximum value of not less than 3 000.

NOTE The choice of A_0 and disinfection temperature will depend upon:

- the intended use of the load items;
- the materials of which the load items are made;
- the nature and extent of the bioburden on the load items with particular reference to heat resistant infective organisms.

Advice will usually be sought from those with responsibility for advising on control of infection.

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 that water remain on the surface of the device to be disinfected.

Conformity to this part of ISO 15883 shall be established by examination of the data obtained from thermometric testing (see 6.3).

4.4 Temperature of internal 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, and the discharge from, the devices is within the limits specified by the manufacturer of the WD and conforms to 4.2 and 4.3;
- the flow of the process fluids at the connection to the instrument is within the limits specified by the manufacturer when tested in accordance with 5.1.2 and 6.3.3;
- the results from the cleaning tests as described in 6.2 are acceptable.

5 Mechanical and control requirements

5.1 Load connectors

5.1.1 Connectors for powered devices

For powered devices and lumen devices, in which the internal surfaces are to be flushed, the WD or load carrier shall be fitted with connectors, specified by the manufacturer of the medical device. For powered devices these connectors shall provide means to drive the instrument during the cycle. The speed of rotation shall be chosen to ensure that all the internal surfaces of axles, gears etc. come into contact with the process fluids for the specified times.

5.1.2 Verification of flow through lumen and powered devices

5.1.2.1 During the washing, disinfection and rinsing stages, it is necessary for the various process fluids to 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:

a) by requiring in the instructions for use that the user:

   1) verifies that all channels allow the free passage of water before the device is loaded into the WD; (Some devices can include channels that require a particular method for verifying that the channel is patent. Careful attention should be paid to specific device manufacturer's instructions regarding these procedures.)

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

b) by the automatic controller providing means to verify the flow of process fluids through each channel. Failure to achieve the required 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 over a range between room temperature and to 60 °C or higher. Adjustment shall be by means of a code, key or tool.

5.2.2 Means shall be provided to pre-set the disinfection temperature over a range between 75 °C and not less than 95 °C. Adjustment shall be by means of a code key or tool.

5.2.3 Means shall be provided to pre-set the disinfection time over the range from one minute to at least 60 min. Adjustment shall be by means of a code, key or tool.

WDs of the pass through type should be employed when practicable to provide separation of cleaned and disinfected items from those awaiting processing.

5.3 Process verification

The WD shall be equipped with a temperature recorder which has sensors and signal processing that are independent from the controller, to record the attainment of the programmed disinfection conditions [see ISO 15883-1:2006, 5.11.4 b)].

6 Testing for conformity

6.1 General

Testing for conformity shall be carried out in accordance with ISO 15883-1:2006, Clause 6.

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

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

The tests shall be carried out in accordance with ISO 15883-1:2006, 6.10 using one or more of the nationally published test soils and methods specified in ISO/TS 15883-5 (For reference, see also References [3] to [14]).

NOTE 1 The attention of users is drawn to local requirements that can require the use of particular test soils and methods.

NOTE 2 The attention of manufacturers is drawn to the user's choice of test soil(s) and method(s) for operational 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 wall and load carriers may not be the same. Where different test soils are used the rationale for the choice of test soil should be documented.

6.3 Thermometric tests

6.3.1 General

The tests shall be performed in accordance with ISO 15883-1:2006, 6.8, with the modifications given in 6.3.2 to 6.3.3.

6.3.2 Load temperature test

6.3.2.1 General

The load temperature test shall be carried out in accordance with the requirements of ISO 15883-1:2006, 6.8.2. The test loads specified below are reference loads which shall be used for type tests and may be used for works test or operational qualification test. A full load of medical devices of the type to be processed, or surrogates for these devices, may be used for operational testing but recourse to the reference loads given below shall be made in case of dispute.

6.3.2.2 Solid devices (e.g. most surgical instruments)

For operational qualification testing, the load shall consist of a mass of stainless steel bolts evenly distributed throughout the loading space to the maximum mass of load specified by the WD manufacturer. The bolts shall:

- conform to ISO 4017;
- be austenitic stainless steel grade conforming to EN 10088-2;
- be M12 × 100 mm with hexagon heads;
- be 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 full load of bowls, dishes and receivers and shall include:

- 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 re-usable 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 full load of glassware and shall include:

- 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.

6.3.2.5 Anaesthetic and respiratory accessories

The test load shall consist of a full load of anaesthetic/respiratory accessories and shall include:

- one breathing tube conforming to ISO 5367;
- one anaesthetic reservoir bag with 15 mm connector, 1,5 l capacity conforming to ISO 5362;
- one anaesthetic reservoir bag with 22 mm connector, 1,5 l capacity conforming to ISO 5362;
- two 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 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;
- a 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 face masks.

6.3.2.6 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.

6.3.2.7 Powered devices

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

6.3.3 Temperature of internal surfaces of devices

For internal surfaces of devices, the following additional test requirements apply.

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

b) Install a flow meter in the pipe to each connector.

c) 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.

The flow meter [see b)] should have a scale range from 0 to (the maximum flow specified by the manufacturer of the WD +20 %) and an accuracy of at least 5 % of the full scale over the temperature range 20 °C to 100 °C.

For operational qualification and performance qualification testing, the four points identified during type testing as representing the range of temperatures shall be used

7 Information to be supplied by the manufacturer

In addition to the information listed in ISO 15883-1:2006, Clause 8, the manufacturer shall provide the purchaser with the following information:

a) range of load supports available and required;

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

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

    1) the time for an operating cycle from a cold start;

    2) the time for an operating cycle from a hot start;

    3) the locations and temperatures of the coolest and hottest parts of the load during thermal disinfection;

d) the temperature and flow rate of process fluids for devices connected so that the inner surface is flushed.

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

In addition to the information listed in ISO 15883-1:2006, Clause 10, the following information shall be requested from the purchaser by the supplier of the WD:

a) whether holders for bowls, dishes and receivers and connectors for hollow devices and/or powered devices need to be installed and in what numbers and locations;

b) the combination of time and temperature 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 WDs for surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils, glassware, etc., in addition to those recommended in ISO 15883-1:2006, Annex A. Other tests or schedules of tests providing equivalent assurance are equally acceptable.

Table A.1 — Summary of test programmes for WDs for surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils, glassware, etc.

Brief description of test	Requirements clause	Test clause	Type test	Works test	Operational qualification	Performance qualification	Routine test
Temperature of internal surfaces of devices	4.4	6.3.3	X	X	X	X	B
X = recommended B = not recommended							

Bibliography

[1] IEC 61010-2-045, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-045: Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields*

[2] EN 868-8, *Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods*

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

[4] BS 2745-3:1993, *Washer-disinfectors for medical purposes. Specification for washer-disinfectors except those used for processing human-waste containers and laundry*

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

[6] ASTM International. Standard test method for determination of effectiveness of cleaning processes for reusable medical instruments using a microbiologic method (simulated use test). ASTM E2314:03, Philadelphia: ASTM International, 2003

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

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

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

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

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

[12] SCHRADER, G. and GÖRISCH, G. The Limitations of Instrument Cleaning Based on Data Collected on vCJD-Risks Posed by Medical Instrument. *Hyg. Med.*, **28**, 2003, pp. 306-309

[13] EDMUNDS, L.M. and RAWLINSON, A. The effect of cleaning on blood contamination in the dental surgery following periodontal procedures. *Australian Dental Journal*, **43**(5), 1998; pp. 349-353

[14] MICHELS, W. Evaluation of a quick test for examining cleaning efficiency of processed surgical and minimally invasive instruments. Hyg. Med., **22**, 1997; pp. 173-184

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: MHD 12 (0502).

Amendments Issued Since Publication

Amendment No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:		*Telephones*
Central	Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	2323 7617 2323 3841
Eastern	1/14, C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi KOLKATA 700054	2337 8499, 2337 8561 2337 8626, 2337 9120
Northern	Plot No. 4-A, Sector 27-B, Madhya Marg, CHANDIGARH 160019	26 50206 265 0290
Southern	C.I.T. Campus, IV Cross Road, CHENNAI 600113	2254 1216, 2254 1442 2254 2519, 2254 2315
Western	Manakalaya, E9 MIDC, Marol, Andheri (East) MUMBAI 400093	2832 9295, 2832 7858 2832 7891, 2832 7892

Branches: AHMEDABAD. BENGALURU. BHOPAL. BHUBANESWAR. COIMBATORE. DEHRADUN. DURGAPUR. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. JAMMU. JAMSHEDPUR. KOCHI. LUCKNOW. NAGPUR. PARWANOO. PATNA. PUNE. RAIPUR. RAJKOT. VISAKHAPATNAM.

Published by BIS, New Delhi