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Washer-disinfectors —

Part 1:
General requirements, definitions and tests

Laveurs désinfecteurs —

Partie 1: Exigences générales, définitions et essais

ICS 11.180.10

ISO/CEN PARALLEL ENQUIRY

This draft International Standard is a draft European Standard developed within the European Committee for Standardization (CEN) and processed under the CEN-lead mode of collaboration as defined in the Vienna Agreement. The document has been transmitted by CEN to ISO for circulation for ISO member body voting in parallel with CEN enquiry. Comments received from ISO member bodies, including those from non-CEN members, will be considered by the appropriate CEN technical body. **Accordingly, ISO member bodies who are not CEN members are requested to send *a copy* of their comments on this DIS directly to CEN/TC 102** (DIN, Burggrafenstraße, 6, D-10787 Berlin) **as well as returning their vote and comments in the normal way to the ISO Central Secretariat.** Should this DIS be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

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English version

Washer-disinfectors - Part 1: General requirements, definitions and tests (ISO/DIS 15883-1:2003)

Laveurs désinfecteurs - Partie 1: Exigences générales, définitions et essais (ISO/DIS 15883-1:2003)

Reinigungs-/Desinfektionsgeräte - Teil 1: Allgemeine Anforderungen, Definitionen und Prüfungen (ISO/DIS 15883-1:2003)

This draft European Standard is submitted to CEN members for second parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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Foreword

This document (prEN ISO 15883-1:2003) has been prepared by Technical Committee CEN/TC 102, "Sterilizers for medical purposes", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

This document is currently submitted to the second parallel Enquiry.

EN ISO 15883 consists of the following parts under the general title *Washer-disinfectors*:

— Part 1: General requirements, definitions and tests

— Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.

— Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

— Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes

Fields of application within the scope of EN ISO 15883 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.

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.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector:

a) this standard provides no information as to whether the washer-disinfector may be used without restriction in any of the member states of the EU or EFTA;

b) it should be noted that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfector remain in force.

Annexes B, C and E are normative. Annexes A, D and ZA are given for information only.

Introduction

This part of prEN ISO 15883 is the first of a series specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to all washer-disinfectors. The requirements given in this part apply to all washer-disinfectors specified in subsequent parts, except insofar as they may be modified or added to by a subsequent part, in which case the requirements of that particular part will apply.

Washer-disinfectors should be used only for processing the type of loads specified by the manufacturer of the washer-disinfector.

In selecting the appropriate washer-disinfector reference should be made both to this standard (prEN ISO 15883-1) and to the relevant subsequent part. The choice of type of washer disinfector, operating cycle or quality of services or process chemicals may be inappropriate for a particular load and means cannot necessarily be provided to detect an incorrect choice or misuse.

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

This standard has been prepared on the basis that each individual washer-disinfector will be subject to validation tests (commissioning and performance qualification on first installation) and that in use continued compliance will be established by periodic monitoring tests carried out by, or on behalf of, the user.

NOTE Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single test method. As an interim measure the specification for test methods includes methods previously used in a number of different countries. It remains the intention of the technical committee to develop a single test method.

1 Scope

This part of prEN ISO 15883 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which may be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

The requirements for washer-disinfectors intended to process specific loads are specified in subsequent parts of this standard. For washer-disinfectors intended to process loads of two or more different types the requirements of all relevant parts of this standard apply.

This standard does not specify requirements intended for machines for use for laundry or general catering purposes.

This standard does not include requirements for machines which are intended to sterilize the load, or which are designated as 'sterilizers'; these are specified in other standards e.g. EN 285.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

prEN ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Metrology and testing (in preparation).*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2000).*

IEC 60417-1, *Graphical symbols for use on equipment — Part 1: Overview and application* .

IEC 60417-2, *Graphical symbols for use on equipment — Part 2: Symbol originals.*

IEC 60584-1, *Thermocouples — Part 1: Reference tables.*

IEC 60751, *Industrial platinum resistance thermometer sensors.*

IEC 80416-1, Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols.

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.*

ISO 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation.*

ISO 7000, *Graphical symbols for use on equipment, index and synopsis.*

ISO 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment.*

European Pharmacopeia. 4th Edition, published 2001, Strasbourg, Council of Europe.

United States Pharmacopeia.

3 Terms and definitions

For the purposes of this part of prEN ISO 15883, the following terms and definitions 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

3.2
automatic controller
device that, in response to pre-determined cycle variables, operates the apparatus sequentially through the required stages of the process or processes

3.3
bedpan washer-disinfector
washer-disinfector intended to be used for the emptying, flushing, cleaning and thermal disinfecting of human waste containers

3.4
bioburden
population of viable microorganisms on a product and/or its container

3.5
calibration
set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standard [EN 285:1996, definition 3.5]

3.6
calorifier
closed vessel, in which water is indirectly heated, by the flow of heated fluid through a heat exchanger, under a pressure greater than atmospheric

3.7
chamber
that part of the washer-disinfector in which the load is processed

NOTE The chamber does not include steam generators, pipework, e.g. drain and fittings from which it can be isolated.

3.8
chemical disinfection
disinfection achieved by the action of one or more chemicals the primary purpose of which is to be microbicidal

3.9
cleaning
removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use

3.10
continuous process machine
machine which automatically transports the load through each stage of the operating cycle

3.11
critical process variables
those process variables for which the values during an operating cycle have been identified by the manufacturer as sufficient to ensure that the cycle meets the performance defined during validation

3.12
cycle complete
indication that the washing and disinfection cycle has been satisfactorily completed and that the disinfected load is ready for removal from the chamber

3.13
cycle control recorder
a device which records the values of one or more control variables as seen by the automatic controller

3.14
***D* value**
exposure time required under a defined set of conditions to cause a 1-logarithm or 90 % reduction in the population of a particular microorganism

3.15
dead volume
volume of pipework which is not purged by the usual flow of liquids during the operating cycle

3.16
disinfection
reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use

3.17
disinfection temperature
minimum temperature of the disinfection temperature band

3.18
disinfection temperature band
range of temperatures, expressed as the disinfection temperature (see 3.17) and the maximum allowable temperature which may prevail throughout the load during the disinfection time

3.19
disinfection time
period for which the critical process variable(s) (e.g. temperature of the load, disinfectant concentration in the chamber) are maintained at or above that specified for disinfection

3.20
door
device provided as a means of closing and sealing the chamber

3.21
double-ended washer-disinfector
washer-disinfector with separate doors for loading and unloading

3.22
endoscope washer-disinfector
washer-disinfector intended to clean and disinfect loads containing flexible endoscopes

3.23
fail safe
attribute of washer-disinfector design, or its associated services, that ensures that a single fault condition will not give rise to a safety hazard

3.24
fault
recognition by the automatic controller that the pre-set process variables for the washer-disinfector cycle have not been attained

3.25
fluid
liquid, gas or vapour

3.26
flushing
removal of gross soiling and/or the contents of a load item, but not necessarily contamination adhering to the surface of the load item, by displacement with water

3.27
free draining
allowing the unimpeded flow of liquids under the influence of gravity towards the discharge point

3.28
holding time
period during which the critical process variables are maintained at or above the value specified

3.29
human waste
excretions and body fluids including faeces, urine, blood, pus, vomit and mucus

3.30
human waste container
re-usable vessel for holding and transporting human waste

3.31
installation qualification
obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

3.32
instrument washer-disinfector
washer-disinfector intended to clean and disinfect loads containing surgical instruments, anaesthetic accessories, hollowware, utensils, glassware and similar items

3.33
load
collective term used to describe all the goods, equipment and materials that are put into a washer-disinfector at any one time for the purpose of cleaning and disinfecting it by an operating cycle

3.34
loading door
door in a double-ended washer-disinfector through which the load is put into the washer-disinfector prior to processing

3.35
medical device
any instrument, apparatus, appliance material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

- investigation, replacement or modification of the anatomy or of a physiological process;

- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [EN 46001:1996, definition 3.1]

3.36
microbial reduction factor
the extent to which the bioburden is reduced in tenfold increments expressed as logarithms (base 10)

3.37
monitoring
measurement of physical variables and comparison of the values obtained with the values specified for the process

3.38
normal operation
operation of the washer-disinfector in accordance with the manufacturer's instructions and with all process parameters within the limits specified by the manufacturer

3.39
operating cycle
complete set of stages that is carried out in the sequence as regulated by the automatic controller

3.40
operating pressure
gauge pressure at which the vessel is operated during normal use

3.41
operational qualification
obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

3.42
override
system by which the operating cycle can be interrupted or modified as necessary

3.43
performance qualification
obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification i.e. that the washer-disinfector produces items cleaned and disinfected to the required standard

3.44
routine test
periodic checking and testing carried out to establish that the operational performance of the washer-disinfector remains within the limits established during validation

3.45
process chemical
formulation of chemical compounds intended for use in a washer-disinfector

NOTE. This includes for example detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners.

3.46
process variable
physical and chemical properties (e. g. times, temperatures, disinfectant concentration, pressures and flows) that influence the efficacy of all stages of the process

3.47
process verification recorder
device that, independently of the automatic controller, records values obtained for some, or all, of the control variables

3.48
recorder
system fitted to the washer-disinfector, or connected to the washer-disinfector, producing a permanent record of information graphically, digitally or electronically

3.49
re-qualification
repeat of part or all of the validation test requirements for the purpose of confirming process reliability

3.50
rinsing
removal of process residues by displacement and dilution with water

3.51
steam generator
vessel designed to contain water and a heating system (e. g. a steam coil or a fully immersed electric element) which is used to heat water to its vapour state

3.52
tank
process vessel, integral to the washer-disinfector, designed to hold fluids that are used during processing

3.53
test microorganism
microbial strain from a recognised culture collection used in microbiological testing of the performance of a washer-disinfector

NOTE A recognised culture collection is an international depository under the Budapest Treaty on 'The International Recognition of the Deposit of Microorganisms for the purpose of Patent and Regulation'.

3.54
test soil
formulation used to test the efficacy of cleaning in a washer-disinfector

3.55
thermal disinfection
disinfection achieved by the action of moist or dry heat

3.56
type test
test programme to verify conformity of a washer-disinfector type to this standard and establish data for reference in subsequent tests

3.57
unloading door
door in a double ended (see 3.21) washer-disinfector through which the load is removed after an operating cycle

3.58
validation
documented procedure for obtaining, recording and interpreting data required to show that a process will comply consistently with predetermined specifications

3.59
verification
confirmation through the provision of objective evidence, that specified requirements have been fulfilled [EN ISO 9000:2000, definition 3.8.4]

3.60
viable microorganism
microorganisms, including viruses, which are capable of multiplication under specified culture conditions

3.61
warning pipe
secondary overflow pipe so fitted that its outlet, whether inside or outside the machine, is in a conspicuous position to indicate an overflow condition

3.62
washer-disinfector
WD
machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice

NOTE This type of machine does not include those designed specifically to wash linen or clothing. Machines intended to sterilize, or designated as 'sterilizers', are specified in other standards e. g. EN 285.

3.63
washing
removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary

3.64
works test
series of tests performed prior to delivery to demonstrate compliance of each WD with its specification

3.65
***z* value**
change in temperature in K required to achieve a tenfold change in the rate of microbial inactivation by a moist heat disinfection process

4 Performance requirements

4.1 General

4.1.1 Compliance with the performance requirements shall be tested in accordance with the methods given in clause 6.

4.1.2 Any item which has been processed in a WD conforming to the EN ISO 15883 series of standards shall have been cleaned, disinfected, rinsed and, when appropriate, dried.

NOTE The performance requirements depend on a number of factors, which include the nature of the item(s) to be processed, the disinfection efficacy required (as determined by the level of risk associated with the use of the item), the nature of the soil to be removed, the nature and extent of any pre-treatment, the temperature, the physical energy (type, power, duration), detergent system, permissible extent of process residues, etc.

4.1.3 The performance specification shall be achieved by an operating cycle under the control of an automatic controller and including, when appropriate, the stages for :

a) cleaning, which may include several stages;

b) disinfecting;

c) arinsing;

d) drying (when appropriate).

NOTE When appropriate two or more stages specified above may be combined as a single stage.

4.1.4 Throughout the operating cycle the rate and extent of any change in temperature, pressure or concentration of process chemicals shall be within limits which will not cause damage to the item(s) which the WD is intended to process (see 8.1 b) 6)).

4.1.5 Criteria for disinfection shall be specified in terms of the microbial reduction factor attained.

NOTE 1 This can be defined by reference to time and temperature for thermal disinfection or as time, temperature and concentration for chemical disinfection.

NOTE 2 Whenever practicable thermal disinfection is preferred. Thermal disinfection processes are more easily controlled and avoid the hazards to staff, patients and the environment that may occur through the use of chemical disinfectants.

NOTE 3 The minimum microbial reduction factor necessary is specified in subsequent parts of the standard.

4.1.6 Within the WD each chamber which is used to contain the load shall be capable of being disinfected under the control of the automatic controller. For single chamber machines this shall be part of the normal operating cycle. For machines with two or more chambers the disinfection cycle may be separate from the normal operating cycle. For multi-chamber machines a disinfection cycle shall not be required for any chamber which is used only for drying.

4.1.7 Chambers in which process fluid may be present during the process cycle shall be free draining (see 6.5.2 and 6.5.4).

4.1.8 Continuous process WDs shall be designed in such a way that the WD, the load carriers and the load are not re-contaminated by the simultaneous processing of other loads.

4.1.9 The environment in contact with the load during the final rinse and drying stages shall be of sufficient purity (chemical and microbial) that it will not adversely affect the load items that the WD is intended to process or Impair the intended use of the items.

4.1.10 The extent and frequency of testing undertaken to verify the purity of the environment shall be determined by risk analysis taking into account the intended use of the processed items and the nature of any control mechanisms eg water treatment systems.

4.2 Cleaning

4.2.1 General

4.2.1.1 Cleaning shall be deemed to have been achieved if, when tested in accordance with 6.10 and with the relevant subsequent Parts of this standard, the reduction of the specified test soil has been determined in accordance with one of the methods given in Annex B and meets he acceptance criteria given in the test method chosen.

4.2.1.2 The manufacturer shall state (see clause 8) the process chemicals and the quality of water (see 6.4) used during product compatibility studies and testing to confirm compliance of the WD with the requirements of this standard.

4.2.2 Flushing stage

The in-flowing water shall be maintained at a temperature low enough to preclude the occurrence of protein coagulation.

NOTE Temperatures higher than 45 °C can cause protein coagulation during the flushing stage and cause cleaning problems.

4.2.3 Washing stage

The temperature of water and aqueous solutions in contact with the load during the washing stage shall be controlled within limits stated by the WD manufacturer.

The temperature of the detergent solutions shall be controlled within the maximum and minimum temperatures stated by the detergent manufacturer.

4.3 Disinfection

4.3.1 Thermal disinfection

4.3.1.1 Thermal disinfection of the load and load carriers shall be deemed to have been achieved if, when tested in accordance with 6.8.2 and the relevant subsequent Parts of this standard, the specified minimum temperature for the specified minimum (holding) time, or the equivalent lethality (A_0, see Annex A), is achieved on all surfaces which are required to be disinfected.

4.3.1.2 Thermal disinfection of the chamber walls shall be deemed to have been achieved if when tested in accordance with 6.8.3 and the relevant subsequent parts of this standard the specified minimum temperature is attained for the specified minimum time, or the equivalent lethality (A_0), is achieved on all chamber walls.

4.3.1.3 The temperature shall be continuously maintained within the specified disinfection temperature band for the specified disinfection time.

4.3.2 Chemical disinfection

4.3.2.1 Chemical disinfection of the load shall be deemed to have been achieved when the load surfaces have been exposed to the specified conditions of chemical disinfectant concentration, temperature, for the required contact time.

4.3.2.2 Chemical disinfection of the chamber walls and load carriers shall be deemed to have been achieved when the specified conditions of chemical disinfection concentration, temperature and contact time have been attained on all chamber walls and load carriers.

4.3.2.3 The conditions of time, temperature and chemical disinfectant concentration shall be those specified, under the conditions of use, by the disinfectant manufacturer.

NOTE Alternatively, a party other than the disinfectant manufacturer should determine the conditions of time, temperature and chemical disinfectant concentration that provide the required microbial reduction factor.

Appropriate additional testing (eg load compatibility, environmental safety, disinfectant stability) shall have been performed also.

4.3.2.4 Microbiological testing shall be employed (see Part 4 of this standard).

4.3.3 Thermal and chemical disinfection

4.3.3.1 The temperature on all surfaces of the load and load carrier shall be within - 0 °C and + 5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.2).

4.3.3.2 The temperatures recorded on the surface of the chamber wall shall be within - 0 °C and + 5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.3).

4.4 Rinsing

4.4.1 The WD shall be provided with a rinsing stage which reduces the concentration of process chemicals on the load to a level not exceeding that specified by the manufacturer, or supplier, of the process chemical(s) as safe in the context of the intended use of the load.

4.4.2 Rinsing shall be deemed to have been achieved if, when tested in accordance with 6.10.4 and with the relevant subsequent Parts of this standard, the reduction of process chemicals has been determined and been shown to have been sufficient for the subsequent intended use of the load.

4.4.3 Means shall be provided, or specified, to ensure that the chemical and microbial quality of the final rinse water will not impair the standard of cleanliness and disinfection (see also 6.4.2).

4.5 Drying

4.5.1 The WD shall, unless otherwise specified, be provided with a drying stage which removes surface moisture from the load.

4.5.2 Drying of the load shall be deemed to have been achieved if, when tested in accordance with 6.12 and the relevant subsequent parts of this standard, no residual water is detected at the end of the drying stage.

4.5.3 Hot air or compressed air used for drying shall be of a quality which shall not impair the specified standard of cleanliness and disinfection.

NOTE. When air free from bacterial or particulate contamination is necessary to fulfil this requirement this can be achieved for example by the use of HEPA (High Efficiency Particulate Air) filtered air.

4.5.4 When air filters are fitted means shall be provided to enable the filtration system to be tested.

The filter used shall be tested for particulate arrest efficiency at the point of use (see 6.11).

NOTE 1 Microbial sampling will not normally be required for the system unless otherwise specified in the purchase contract.

NOTE 2 For applications where it is important that the air is free from microbial contamination it may be necessary to carry out testing during the process or before and/or after each cycle.