



ISO 15883-2

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

**Second edition
2024-11**

This is a preview of ISO 15883-2:2024. [Click here to purchase the full version from the ANSI store.](#)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of ISO 15883-2:2024. [Click here to purchase the full version from the ANSI store.](#)

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Performance requirements	3
4.1 General.....	3
4.2 Cleaning.....	4
4.3 Disinfecting.....	4
4.4 Temperature of inner surfaces of processed devices.....	5
4.5 Water quality.....	5
5 Mechanical and control requirements	5
5.1 Lumen and powered devices.....	5
5.1.1 Irrigation.....	5
5.1.2 Verification of flow through lumen and powered devices.....	6
5.2 Control systems.....	6
5.3 Process verification.....	6
6 Testing for conformity	6
6.1 General.....	6
6.2 Tests for soil removal from chamber walls, load carrier(s) and load.....	7
6.3 Thermometric tests.....	7
6.3.1 General.....	7
6.3.2 Temperature of outer surfaces of devices.....	7
6.3.3 Temperature of inner surfaces of devices.....	8
6.4 Pressure and flow measurement.....	9
7 Information to be provided for the WD	9
8 Information to be requested from the purchaser by the supplier of the WD	9
Annex A (informative) Summary of test programmes	10
Annex B (informative) Guidance on the designation of a medical device to a product family for cleaning and thermal disinfection processes	11
Bibliography	14

This is a preview of ISO 15883-2:2024. [Click here to purchase the full version from the ANSI store.](#)

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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

This is a preview of ISO 15883-2:2024. [Click here to purchase the full version from the ANSI store.](#)

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.