
Washer-disinfectors —

Part 4:

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

Laveurs désinfecteurs —

*Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à
la désinfection chimique des endoscopes thermolabiles*

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Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

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

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

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

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

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

Introduction

This introduction is intended to be read in conjunction with the introduction to ISO 15883-1.

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

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

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

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

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

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

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