

DIN EN ISO 15883-7



ICS 11.080.10

Supersedes: see below

**Washer-disinfectors –
Part 7: Requirements and tests for washer-disinfectors employing
chemical disinfection for non-invasive, non-critical thermolabile medical
devices and healthcare equipment (ISO 15883-7:2016);
English version EN ISO 15883-7:2016,
English translation of DIN EN ISO 15883-7:2016-10**

Reinigungs-Desinfektionsgeräte –

Teil 7: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für nicht invasive, nicht kritische thermolabile Medizinprodukte und Zubehör im Gesundheitswesen (ISO 15883-7:2016);

Englische Fassung EN ISO 15883-7:2016,

Englische Übersetzung von DIN EN ISO 15883-7:2016-10

Laveurs désinfecteurs –

Partie 7: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des dispositifs médicaux thermosensibles, non invasifs et non critiques et des équipements de soins de santé (ISO 15883-7:2016);

Version anglaise EN ISO 15883-7:2016,

Traduction anglaise de DIN EN ISO 15883-7:2016-10

Supersedes DIN 58955-1:2003-01, DIN 58955-2:2005-07, DIN 58955-3:1998-09, DIN 58955-4:2006-03, DIN 58955-6:2001-03 and DIN 58955-7:2001-03

Document comprises 48 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

A comma is used as the decimal marker.

National foreword

This document (EN ISO 15883-7:2016) has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” in collaboration with Technical Committee CEN/TC 102 “Sterilizers for medical purposes” (Secretariat: DIN, Germany).

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-04-09 AA *Reinigungs-Desinfektionsgeräte*.

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

- *Part 1: General requirements, terms and definitions and tests*
- *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, 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 thermolabile endoscopes*
- *Part 5: Test soils and methods for demonstrating cleaning efficacy [Technical Specification]*
- *Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment*
- *Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment*

The DIN Standards corresponding to the International Standards referred to in this document are as follows:

ISO 11737-1	DIN EN ISO 11737-1
ISO 15883-1	DIN EN ISO 15883-1
ISO 15883-2	DIN EN ISO 15883-2
ISO 15883-3	DIN EN ISO 15883-3
ISO 15883-4	DIN EN ISO 15883-4
ISO/TS 15883-5	DIN ISO/TS 15883-5
IEC 61010-2-040	DIN EN 61010-2-040 (VDE 0411-2-040)

Amendments

This standard differs from DIN 58955-1:2003-01, DIN 58955-2:2005-07, DIN 58955-3:1998-09, DIN 58955-4:2006-03, DIN 58955-6:2001-03 and DIN 58955-7:2001-03 as follows:

- a) the DIN 58955 series of standards dealing with decontamination equipment for medical use served as a basis for the new standards project at CEN and ISO; the DIN EN ISO 15883 standards series has been taken as the basis for the document structure;
- b) terms and definitions of DIN 58955-1 have been brought in line with DIN EN ISO 15883-1 and ISO/TS 11139;
- c) requirements for devices, equipment and test methods have been substantially adopted from the DIN 58955 series of standards, but partly increased (see e.g. thermal methods);
- d) the requirements for devices and equipment formerly given in DIN 58955-2 are now specified in Clauses 5 and 6 and via reference to DIN EN ISO 15883-1, specific material requirements having been dispensed with to avoid design limitations;
- e) performance requirements formerly given in DIN 58955-3 are now specified in Clause 4, Subclauses 6.7 and 6.8 (see also Annex A), and via reference to DIN EN ISO 15883-1;
- f) requirements for biological indicators formerly given in DIN 58955-4 are now specified primarily in Annexes B to E;
- g) requirements for operation (commissioning/maintenance) formerly given in DIN 58955-6 and for services supply formerly given in DIN 58955-7 are now specified primarily in Clause 4 and via reference to DIN EN ISO 15883-1;
- h) the standard has been prepared under a mandate (see Annex ZA).

Previous editions

DIN 58955-1: 1992-09, 2003-01
DIN 58955-2: 1998-09, 2005-07
DIN 58955-3: 1998-09
DIN 58955-4: 1998-09, 2006-03
DIN 58955-6: 2001-03
DIN 58955-7: 2001-03