



SLOVENSKI STANDARD
oSIST prEN ISO 15883-6:2025
01-april-2025

Čistilno-dezinfekcijske naprave - 6. del: Zahteve in preskusi čistilno-dezinfekcijskih naprav s toplotno dezinfekcijo za nenujne medicinske pripomočke in zdravstveno opremo (ISO/DIS 15883-6:2025)

Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for noncritical medical devices and health care equipment (ISO/DIS 15883-6:2025)

Reinigungs-Desinfektionsgeräte - Teil 6: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für nicht kritische Medizinprodukte und Zubehör im Gesundheitswesen (ISO/DIS 15883-6:2025)

Laveurs désinfecteurs - Partie 6: Exigences et essais pour les laveurs désinfecteurs utilisant une désinfection thermique pour les dispositifs médicaux non invasifs, non critiques et pour l'équipement de soins de santé (ISO/DIS 15883-6:2025)

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ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

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DRAFT International Standard

ISO/DIS 15883-6

Washer-disinfectors —

Part 6: Requirements and tests for washer- disinfectors employing thermal disinfection for noncritical medical devices and health care equipment

Laveurs désinfecteurs —

*Partie 6: Exigences et essais pour les laveurs désinfecteurs
utilisant une désinfection thermique pour les dispositifs médicaux
non invasifs, non critiques et pour l'équipement de soins de santé*

ICS: 11.080.10

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Foreword

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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 15883-6:2011), which has been technically revised.

The main changes are as follows:

- change of title to reflect application to non-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 and ISO 15883-5;
- the temperatures recorded on the surface of the load, load carrier(s) and chamber walls follow the temperature profile specified for the disinfection stage and are within 0 °C and +10 °C as specified in [4.3.4](#);
- cleaning testing carried out in triplicate in accordance with ISO 15883-1 using the appropriate test method(s) and test soil(s) as specified in ISO 15883-5;
- addition of water quality specified in [4.4](#);
- updating of Bibliography.

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

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