भारतीय मानक

धोनेवाले कीटाणुशोधक भाग ५ सफाई प्रभावकारिता का प्रदर्शन करने के लिए प्रदर्शन आवश्यकताएँ और परीक्षण विधि मानदंड (ISO 15883-5:2021, संशोधित)

Indian Standard

Washer-Disinfectors
Part 5 Performance Requirements and Test Method Criteria for
Demonstrating Cleaning Efficacy
(ISO 15883-5:2021, MOD)

ICS 11.080.10

Hospital Equipment and Surgical Disposal Sectional Committee, MHD 12

NATIONAL FOREWORD

This Indian Standard (Part 5) which is identical with ISO 15883-5:2021, 'Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy' issued by the International Organization for Standardization was adopted by Bureau of Indian Standards on the recommendation of the Hospital Equipment and Surgical Disposal Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

This Indian Standard supersedes IS/ISO/TS 15883-5:2005 which was published in 2019 as an Identical adoption of ISO/TS 15883-5:2005. After publication of this standard, IS/ISO/TS 15883-5:2005 stands withdrawn.

The text of ISO Standard, ISO 15883-5:2021 'Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy', has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	Corresponding Indian Standard	Degree of Equivalence
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process		Modified
ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	IS/ISO 10993-5 : 2009, Biological Evaluation of Medical Devices Part 5 Tests for in vitro Cytotoxicity	Identical
ISO 15883-1 Washer-disinfectors — Part 1: General requirements, terms and definitions and tests	,	Identical

The standard also makes a reference to the BIS Certification Marking of the product. Details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (*Second Revision*). The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

NATIONAL ANNEX A

(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.