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English Version

**Washer-disinfectors - Part 5: Test soils and methods for
demonstrating cleaning efficacy (ISO/TS 15883-5:2005)**

Laveurs désinfecteurs - Partie 5: Terrains d'essai et
méthodes pour démontrer l'efficacité de nettoyage (ISO/TS
15883-5:2005)

Prüfanschmutzungen und -verfahren zum Nachweis der
Reinigungswirkung von Reinigungs-/Desinfektionsgeräten
(ISO/TS 15883-5:2005)

This Technical Specification (CEN/TS) was approved by CEN on 1 March 2005 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (CEN ISO/TS 15883-5:2005) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this CEN Technical Specification: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 15883-5 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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]

Introduction

Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single internationally acceptable test method. As an interim measure, the Technical Committees responsible for the ISO 15883 series of standards on washer-disinfectors (ISO/TC 198 and CEN/TC 102) have decided that the cleaning efficacy of washer-disinfectors claiming compliance with the ISO 15883 series of standards be demonstrated by referring to the test soils and methods that are currently used in a number of different countries. For the convenience of the user of the ISO 15883 series of standards, these test soils and methods are described in this Technical Specification. It should be noted that it remains the intention of the Technical Committees to develop a single test method.

Washer-disinfectors —

Part 5:

Test soils and methods for demonstrating cleaning efficacy

1 Scope

This Technical Specification includes the test soils and methods that can be used to demonstrate the cleaning efficacy of washer-disinfectors (WD) according to the ISO 15883 series of standards.

The inclusion of the test soils and methods in this Technical Specification does not indicate that they are of equivalent sensitivity in their determination of cleaning efficacy.

Acceptance criteria are included, based on visual inspection and/or a microbiological end-point as stated for each method. Where chemical detection of residual soiling is required/sought, methods can be complemented by the specific determination of a residual component of the applied test soil.

NOTE 1 The test soils and methods included in this Technical Specification are sourced from national standards and published documents submitted by member bodies of the Technical Committee preparing this Technical Specification. They have been edited only to provide a uniform format within this Technical Specification.

NOTE 2 An example of this is the use of the peroxidase test (see Annex J) to detect residual blood (haemoglobin) from the test soil applied to surgical instruments or flexible endoscopes (e.g. using the method described in Annex G). See also ISO 15883-1:2005, Annex D.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 15883-1:2005, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

3 Applicability

3.1 Where any of the test methods specified below deviate from the test method for cleaning efficacy specified in ISO 15883-1, the method given in ISO 15883-1 shall be used (see ISO 15883-1:2005, 6.10). Cleaning efficacy, for example, shall be determined after exposure to only the cleaning part of the operating cycle.

3.2 Table 1 includes a summary of the test soils which are included in this Technical Specification. The test soils are listed for the specific type of WD loads for which they were specified; the same test soils may be used also for other types of loads: for example, soils specified for surgical instrument may be used for other metal components.