Technical Specification

ISO/TS 17664-3

First edition
2026-06

Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices —

Part 3: Guidance on the designation of a reusable medical device to a cleaning classification

Traitement de produits de soins de santé — Informations relatives au traitement des dispositifs médicaux à fournir par le fabricant du dispositif —

Partie 3: Recommandations sur la désignation d'un dispositif médical réutilisable dans une classification de nettoyage

Reference number
ISO/TS 17664-3:2026(en)

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Published in Switzerland

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Foreword

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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).

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 204, *Sterilization of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 17664 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

ISO 17664-1 and ISO 17664-2 address the medical device manufacturer's labelling requirements. Typically, these requirements are mandated by law or government regulation to be validated to demonstrate effective processes. This document is intended to bridge the gap between the manufacturer of reusable medical devices and the facility responsible for medical device processing.

ISO 17664-1 and ISO 17664-2 specify requirements for the information to be provided by the medical device manufacturer for processing. ISO 17665 gives specificity for designation to a product family or master product, but this is for moist heat sterilization and not for cleaning.

Product family and master product are used within a number of documents (i.e. ISO 17664-1 and ISO 17664-2, AAMI TIR12 and ANSI/AAMI ST98). These documents use the terminology, but do not provide guidance to inform the medical device manufacturer as to how to define product family or designate the master product using objective evidence.

The connection between the medical device manufacturer and the processing facility is intended to be communicated through the instructions for use (IFU). In addition to providing guidance to the manufacturer, this document provides the guidance to the processing facility to establish cleaning workflows based on medical device cleaning classification category within the clinical setting. This allows verification that the cleaning instructions can be performed effectively for all reusable medical devices.

As the variability in design features for reusable medical devices continues to increase, guidance is needed to establish appropriate medical device cleaning classification.

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Part 3: Guidance on the designation of a reusable medical device to a cleaning classification

1 Scope

This document gives guidance on designating medical devices to cleaning classification categories, attributes used for medical device cleaning classification category, and designation of a cleaning process.

The cleaning classification category is comprised of two parts:

a) designate medical devices to a product family;

b) designate product families to cleaning processes.

NOTE 1 This allows grouping of medical devices into cleaning classification categories during cleaning and identification of master products during cleaning validation.

This document is applicable to manufacturers devising cleaning methods and instructions for processing. It also applies to any processing facility where medical devices are cleaned.

This document does not cover processing of single-use medical devices provided as sterile before use and textile devices.

NOTE 2 Manual cleaning steps before automated cleaning do not include steps that are considered point of use treatment that can be specified.

NOTE 3 Microbiocidal processes (sanitization, disinfection, sterilization) are not in the scope of the medical device cleaning classification categories.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/