

STN P	Úprava výrobkov na zdravotnú starostlivosť Informácie poskytované výrobcom zdravotníckych pomôcok na úpravu zdravotníckych pomôcok Časť 3: Pokyny k zaradeniu opakovane použiteľnej zdravotníckej pomôcky do klasifikácie čistenia (ISO/TS 17664-3: 2026)	STN P CEN ISO/TS 17664-3 85 6536
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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 (ISO/TS 17664-3:2026)

Táto norma obsahuje anglickú verziu európskej normy.

This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/26

Táto predbežná slovenská technická norma je určená na overenie. Prípadné pripomienky pošlite do júla 2028 Úradu pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky.

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CEN ISO/TS 17664-3

July 2026

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English Version

**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 (ISO/TS 17664-3:2026)**

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 (ISO/TS 17664-3:2026)

Aufbereitung von Produkten für die
Gesundheitsfürsorge - Vom Medizinprodukt-Hersteller
bereitzustellende Informationen für die Aufbereitung
von Medizinprodukten - Teil 3: Leitfaden für die
Einstufung eines wiederverwendbaren
Medizinprodukts in eine quantitative Reinigungsklasse
(ISO/TS 17664-3:2026)

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CEN ISO/TS 17664-3:2026 (E)

Contents	Page
European foreword.....	3

European foreword

This document (CEN ISO/TS 17664-3:2026) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices" the secretariat of which is held by BSI.

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Endorsement notice

The text of ISO/TS 17664-3:2026 has been approved by CEN as CEN ISO/TS 17664-3:2026 without any modification.



Technical Specification

ISO/TS 17664-3

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*

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ISO/TS 17664-3:2026(en)



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ISO/TS 17664-3:2026(en)**Contents**

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Risk analysis	4
5 Product families	4
5.1 General	4
5.2 Geometric design features	5
5.3 Materials of construction	5
5.4 Clinical use	5
5.5 Type of cleaning process	5
6 Cleaning classification categories	5
6.1 General	5
6.2 Manual cleaning	6
6.2.1 Category M1 medical devices	6
6.2.2 Category M2 medical devices	6
6.2.3 Category M3 medical devices	6
6.3 Automated cleaning	6
6.3.1 Category A1 medical devices	6
6.3.2 Category A2 medical devices	6
6.3.3 Category A3 medical devices	6
7 Application of cleaning classification category	6
7.1 General	6
7.2 Medical device complexity	7
7.3 Cleaning risk mitigation	7
8 Processing resources for categories and families of medical devices	7
8.1 General	7
8.2 Category M1 and A1 medical devices	7
8.3 Category M2 and A2 medical devices	7
8.4 Category M3 and A3 medical devices	7
Annex A (informative) Guidance on product families	9
Bibliography	12

ISO/TS 17664-3:2026(en)**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.

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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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).

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ISO/TS 17664-3:2026(en)**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.

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

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.

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