SLOVENSKI STANDARD
SIST EN ISO 17665:2024

01-julij-2024

Sterilizacija izdelkov za zdravstveno nego - Vlažna toplota - Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO 17665:2024)

Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)

Sterilisation von Produkten für die Gesundheitsfürsorge - Feuchte Hitze - Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 17665:2024)

Stérilisation des produits de santé - Chaleur humide - Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux (ISO 17665:2024)

Ta slovenski standard je istoveten z: **EN ISO 17665:2024**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 17665:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17665

May 2024

ICS 11.080.01

Supersedes EN ISO 17665-1:2006, CEN ISO/TS 17665-2:2009

English Version

Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)

Stérilisation des produits de santé - Chaleur humide - Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux (ISO 17665:2024)

Sterilisation von Produkten für die Gesundheitsfürsorge - Feuchte Hitze - Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 17665:2024)

This European Standard was approved by CEN on 3 December 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

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European foreword

This document (EN ISO 17665:2024) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17665-1:2006 and CEN ISO/TS 17665-2:2009.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA or ZB, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 17665:2024 has been approved by CEN as EN ISO 17665:2024 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail. In this context, the definition of 'medical device' in this standard is a modified version of the definition prepared by the Global Harmonization Task Force with modification to the Note in the definition.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — – Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.3	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the medical device is safe and performs as intended after treatment. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This General Safety and Performance Requirement is addressed only with regard to devices for which treatment by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of a specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of a specific microbial state using moist heat are not covered.
11.4 first sentence only	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of sterility by moist heat are not covered. Evidence that the integrity of the packaging

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		is maintained to the point of use is not covered.
11.5	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility is not covered. Aspects of manufacture other than those related to attainment of sterility using moist heat are not covered.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 11140-1	ISO 11140-1:2014	Sterilization of health care products — Chemical indicators — Part 1: General requirements	EN ISO 11140-1:2014
ISO 11140-3	ISO 11140-3:2007	Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	EN ISO 11140-3:2009
ISO 11140-4	ISO 11140-4:2007	Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	EN ISO 11140-4:2007
ISO 11140-5	ISO 11140-5:2007	Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests	None For applicable standard edition see Column 2
ISO 11140-6	ISO 11140-6:2022	Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers.	EN ISO 11140-6:2022
ISO 11607-1	ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020+A11:2022
ISO 11607-2	ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020+A11:2022
ISO 11737-1	ISO 11737-	Sterilization of health care	EN ISO 11737-1:2018+A1:2021

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
	1:2018/amd1:2021	products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	
ISO 11737-2	ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	EN ISO 11737-2:2020
ISO 11138-1	ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements	EN ISO 11138-1:2017
ISO 11138-3	ISO 11138-3:2017	Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes	EN ISO 11138-3:2017

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document and are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning *in vitro* diagnostic medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZB.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746, the differences shall be indicated in the Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail. In this context, the definition of 'medical device' in this standard is a modified version of the definition prepared by the Global Harmonization Task Force with modification to the Note in the definition.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be 'reduced as far as possible', 'reduced to a level as low as reasonably practicable', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'prevented' or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

Table ZB.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/746 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.2	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This General Safety and Performance Requirement is addressed only with regard to devices for which treatment by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility or another specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of sterility or another specific microbial state using moist heat are not covered.
11.3	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		Standard. Packaging for maintenance of sterility is not covered. Aspects of manufacture other than those related to attainment of sterility using moist heat are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.