SLOVENSKI STANDARD
SIST EN ISO 10993-7:2026

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SIST EN ISO 10993-7:2009
SIST EN ISO 10993-7:2009/A1:2022
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Biološko ovrednotenje medicinskih pripomočkov - 7. del: Ostanki po sterilizaciji z etilenoksidom (ISO 10993-7:2026)

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2026)

Biologische Beurteilung von Medizinprodukten - Teil 7: Ethylenoxid-Sterilisationsrückstände (ISO 10993-7:2026)

Évaluation biologique des dispositifs médicaux - Partie 7: Résidus de stérilisation à l'oxyde d'éthylène (ISO 10993-7:2026)

Ta slovenski standard je istoveten z: **EN ISO 10993-7:2026**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-7:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-7

May 2026

ICS 11.100.20

Supersedes EN ISO 10993-7:2008, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-7:2008/A1:2022

English Version

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2026)

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This European Standard was approved by CEN on 17 February 2026.

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 10993-7:2026) has been prepared by Technical Committee ISO/TC 194 "Biological and clinical evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 “Biological and clinical evaluation of medical devices” the secretariat of which is held by DIN.

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 2026, and conflicting national standards shall be withdrawn at the latest by November 2026.

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 10993-7:2008, EN ISO 10993- 7:2008/AC:2009, EN ISO 10993-7:2008/A1:2022.

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, 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 10993-7:2026 has been approved by CEN as EN ISO 10993-7:2026 without any modification.

Annex ZA
(informative)

Relationship between this European Standard 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 harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745, 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) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this document 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
10.1 (a), (b), (d), (e), and (h)	4, 5	This document addresses the Ethylene oxide (EO) sterilization method rather than choice of materials for a medical device or the method's impact on the properties of a material. Flammability and mechanical or physical (e.g., surface) properties are not covered. This document provides requirements for a toxicological risk assessment process for EO sterilization residues present in or on, or released from, a medical device. EO sterilization residues have the capacity to interact with biological tissues, cells or body fluids and the document provides a process for assessing the likelihood of any associated harm to health arising as a result of exposure to EO sterilization residues during the intended use of the medical device. Such an assessment can confirm the absence of appreciable toxicological risk and verify that exposure to EO sterilization residues from the device should not result in an adverse reaction in biological tissues, cells or body fluids. The document only addresses toxicological risks associated with the use of EO as a processing material; the toxicological risk assessment of all other processing materials used and the impact of processes on the properties of the materials of manufacture is not covered by this document. The document provides requirements for a process for measuring the level of potential exposure to EO sterilization residues in or on a medical device (4.4) and for confirming that the exposure estimate meets specifications (allowable limits, 4.3) determined to be without appreciable harm to health, defined with respect to residues of EO and its reaction product ECH only. The allowable limits are chemical specifications based on kinetic modelling. The document specifies requirements for the release of medical devices for use following verification that allowable limits are met (Clause 5).

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
10.2	4, 5	The document addresses risks posed by EO sterilization residues. This document provides methods for manufacturers to control the risks posed by exposure to EO sterilization residues to the patient during normal product use, taking into account the intended use as well as duration and frequency of exposure. Since EO sterilization residues are a subset of residues which are associated with medical devices, the GSPR is only covered by this document with respect to EO sterilization residues. The document specifies maximum allowable doses of EO sterilization residuals delivered to patients regarding different patient populations but does not provide maximum allowable doses of EO sterilization residuals to persons involved in the transport, storage or use of the device. Maximum allowable doses for special situations regarding different contacting tissues are addressed. Devices or components that have neither direct nor indirect patient contact are not addressed.
10.4.1 1st paragraph	4, 5	The document addresses risks posed by processing residues associated with the EO sterilization process. This document provides a method for manufacturers to estimate the release of EO sterilization residues from the medical devices and provides means to demonstrate that they have been reduced to a level that will be without appreciable harm to health. However, the GSPR is only partly covered by this document, since EO sterilization residues are only a subset of the processing residues associated with the manufacture of a medical device. This document also does not provide requirements for design and manufacture, nor does it address risks associated with particles, including wear debris and degradation products from medical devices.
10.4.1 2nd paragraph	4, 5	The document is applicable for all medical devices in direct or indirect contact to the patient and includes the listed contact categories. This document does not provide a method to determine whether EO is present in concentrations above 0,1% weight by weight (w/w) in devices, those parts thereof or those materials used therein.
10.4.1 (a)	4, 5	The document addresses ethylene oxide which is

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		listed in Part 3 of Annex VI of Regulation (EC) No 1272/2008. EO may cause genetic defects (Muta. 1B), may cause cancer (Carc. 1B), may damage fertility and is suspected of damaging the unborn child (Repr. 1B).
10.4.2 (a), (c)	4, 5	The document provides methods for the analysis and estimation of potential patient or user exposure to EO. The document specifies maximum allowable doses of EO residuals delivered to patients regarding different patient populations that can form a basis for a justification regarding the presence of the substance.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 10993-1:2025	ISO 10993-1:2025	Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process	EN ISO 10993-1:2025
ISO 10993-23:2021	ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation	EN ISO 10993-23:2021

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. 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.

Table ZA.3 — Prevailing terms of Regulation (EU) 2017/754 for the use of this European standard under that Regulation

Term used in this EN	Clause(s)/sub-Clause(s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/ Consequences
Implant	3.11	Article 2 (5)	The definition is substantially equivalent. The difference between “implant” and “implantable device” in the MDR is only a clarification and this is already implicit in the definition provided in 3.11.

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.

International Standard

ISO 10993-7

Biological evaluation of medical devices —

Part 7: Ethylene oxide sterilization residuals

Évaluation biologique des dispositifs médicaux —

Partie 7: Résidus de stérilisation à l'oxyde d'éthylène

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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.

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 194, *Biological and clinical evaluation of medical devices,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10993-7:2008), which has been technically revised. It also incorporates the Amendment ISO 10993-7:2008/Amd 1:2019 and the Technical Corrigendum ISO 10993-7:2008/Cor 1:2009.

The main changes are as follows:

— allowable limits and extraction conditions have been derived based on the patient population and the duration of use;

— the use of a risk assessment to establish allowable limits has been permitted;

— additional guidance on product release has been provided;

— additional guidance on determining residuals and the factors that affect residual has been provided.

A list of all parts in the ISO 10993 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

As noted in the introduction to ISO 11135, when determining the suitability of ethylene oxide (EO) for sterilization of medical devices, it is important to ensure that the levels of residual EO and ethylene chlorohydrin (ECH) pose a minimal risk to the patient in intended product use. Therefore, it is important that the use of alternative materials and sterilization processes are considered during product design and development. EO is known to exhibit a number of biological effects. In the development of this document, consideration was given to these effects, which include irritation, organ damage, mutagenicity, carcinogenicity, and reproductive effects in humans and animals. Similar consideration was given to the harmful effects of ECH and ethylene glycol (EG). ECH can be formed when EO comes into contact with free chloride ions, whereas EG is a hydrolytic reaction product of EO and water. In practice, for most devices, exposure to EO and ECH is considerably lower than the maximum allowable limits established according to this document. No allowable limits are set for EG because risk assessment indicated that when EO residuals are controlled, it is unlikely that biologically significant residuals of EG would be present.

Requirements herein are in addition to the biological evaluation requirements as indicated in ISO 10993-1. The biological evaluation, combined with the EO-sterilization process residual limits, form the justification that an EO-sterilized device is safe for its anticipated contact duration. Maximum allowable residuals for ECH, when ECH has been found to be present in medical devices sterilized with EO, are also specified. Local effects (e.g. irritation) have been considered and are incorporated in the TCL as given in 4.3.6.2 and Annex D for EO, and in 4.3.6.3 and Annex E for ECH.

In this edition of this document (i.e. ISO 10993-7:2026), an uncertainty factor approach is used to derive EO and ECH exposure duration-specific tolerable intake (TI) values (expressed in µg/kg/d). Furthermore, this edition of this document (i.e. ISO 10993-7:2026) introduces the conversion of each EO and ECH TI value into subpopulation-specific cumulative exposure-allowable limit values (expressed in milligrams per device), which are used to determine the extent that EO and ECH, extracted under clinically relevant conditions and time-periods, needs to be reduced post-sterilization.

This edition of this document (i.e. ISO 10993-7:2026) applies a different approach as compared to ISO 10993-17:2023 to establishing allowable limits to make it useful for development, validation, and routine control of ethylene oxide sterilization in the manufacture of finished medical devices with focus on the risk assessments associated with three chemical constituents that are potentially left in medical devices sterilized with ethylene oxide. This document extends this knowledge further by calculating the largest amount of EO, ECH or EG that can be present in a medical device such that it would always meet the requirements of ISO 10993-17 when that device has been exposed to the validated sterilization cycle parameters. This maximum amount or allowable limit is expressed in milligrams per device deemed acceptable when taken into the body through exposure to that medical device. These allowable limits will help determine the appropriate sterilization parameters such as sterilant gas concentration and dwell, as well as aeration temperature and hold time when validating the sterilization process to be used for a product or group of products. Furthermore, the allowable limits can be used by regulatory bodies, manufacturers, and processors to optimize processes and aid in the selection and qualification of alternative materials in order to protect patient health.