ICS 11.100.20 SLOVENSKÁ TECHNICKÁ NORMA Február 2026

STN	**Biologické hodnotenie zdravotníckych pomôcok Časť 12: Príprava vzorky a referenčné materiály (ISO 10993-12: 2021/Amd 1: 2025) Zmena A1**	**STN EN ISO 10993-12/A1** 85 6510

Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

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. 01/26

Obsahuje: EN ISO 10993-12:2021/A1:2025, ISO 10993-12:2021/Amd 1:2025

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-12:2021/A1

September 2025

ICS 11.100.20

English Version

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials - Amendment 1 (ISO 10993 12:2021/Amd 1:2025)

Évaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et matériaux de référence - Amendement 1 (ISO 10993 12:2021/Amd 1:2025)

Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien - Änderung 1 (ISO 10993 12:2021/Amd 1:2025)

This amendment A1 modifies the European Standard EN ISO 10993-12:2021; it was approved by CEN on 24 August 2025.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 10993-12:2021/A1:2025 E

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European foreword

This document (EN ISO 10993-12:2021/A1:2025) 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 Amendment to the European Standard EN ISO 10993-12:2021 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2026, and conflicting national standards shall be withdrawn at the latest by March 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 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 10993-12:2021/Amd 1:2025 has been approved by CEN as EN ISO 10993-12:2021/A1:2025 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)/subclause(s) of this EN	Remarks/Notes
10.1 (a), (b) first half sentence and (d)	4, 5, 6, 7, 8, 9, 10 and 11	10.1 is only partly covered by this document, since the document does not provide requirements on design and manufacture, nor does it provide methods to fulfil characteristics and performance requirements. However, this document provides a means of preparing samples, and when used in conjunction with other relevant parts from the EN ISO 10993 series it can provide information on “toxicity”, on “compatibility with tissues, cells and body fluids” as well as on the “impact of processes on material properties”. Flammability is not covered. For 10.1 (b), ADME (Absorption, Distribution, Metabolism and Excretion) are not covered. For 10.1 (d), impact of processes on material properties is covered as far as they could affect the biocompatibility, while general impact on mechanical stability is not covered.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
10.2	4, 5, 6, 7, 8, 9, 10 and 11	10.2 is only partly covered by this document, since the document does not provide requirements on design and manufacture and does not oblige to minimize risk. However, this document provides a means of preparing samples to assess conformity with this General Safety and Performance requirement in conjunction with other relevant parts of EN ISO 10993 series, which describe tests to assess specific toxicological risks, for the design and manufacture of medical devices. Packaging is only covered with respect to packaging migrants in the final product. Risks from residues to person involved in the transport or storage of medical devices are not covered.
10.4.1 (First paragraph only)	4, 5, 6, 7, 8, 9, 10 and 11	10.4.1 is only partly covered by this document, since the document does not provide requirements on design and manufacture and does not oblige to reduce as far as possible the risk. However, this document provides a means of preparing samples of medical devices to assess conformity with General Safety and Performance requirement in conjunction with other relevant parts of EN ISO 10993 series, which describe tests to assess specific toxicological risks.

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	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
ISO 10993-18	ISO 10993-18:2020 ISO 10993-18:2020/Amd 1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	EN ISO 10993-18:2020 EN ISO 10993-18:2020/A1:2023
ISO/TS 10993-19	ISO/TS 10993-19:2020	Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials	For applicable standard edition see Column 2
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021

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.

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 10993-12

Fifth edition
2021-01

AMENDMENT 1
2025-08

Biological evaluation of medical devices —

Part 12: Sample preparation and reference materials

AMENDMENT 1

Évaluation biologique des dispositifs médicaux —
Partie 12: Préparation des échantillons et matériaux de référence
AMENDEMENT 1

Reference number
ISO 10993-12:2021/Amd.1:2025(en)

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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 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).

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).

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.

ISO 10993-12:2021/Amd.1:2025(en)

Biological evaluation of medical devices —

Part 12: Sample preparation and reference materials

AMENDMENT 1

Clause 2

Replace the text of Clause 2 with:

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

ISO/TS 10993-19, *Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials*

ISO 14971, *Medical devices — Application of risk management to medical devices*