SLOVENSKI STANDARD
SIST EN ISO 10993-15:2023

01-september-2023

Nadomešča:
SIST EN ISO 10993-15:2009

Biološko ovrednotenje medicinskih pripomočkov - 15. del: Identifikacija in ugotavljanje količine razgradnih produktov iz kovin in zlitin (ISO 10993-15:2019)

Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2019)

Biologische Beurteilung von Medizinprodukten - Teil 15: Qualitativer und quantitativer Nachweis von Abbauprodukten aus Metallen und Legierungen (ISO 10993-15:2019)

Évaluation biologique des dispositifs médicaux - Partie 15: Identification et quantification des produits de dégradation issus des métaux et alliages (ISO 10993-15:2019)

Ta slovenski standard je istoveten z: **EN ISO 10993-15:2023**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-15:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-15

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ICS 11.100.20

Supersedes EN ISO 10993-15:2009

English Version

Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2019)

Évaluation biologique des dispositifs médicaux - Partie 15: Identification et quantification des produits de dégradation issus des métaux et alliages (ISO 10993-15:2019)

Biologische Beurteilung von Medizinprodukten - Teil 15: Qualitativer und quantitativer Nachweis von Abbauprodukten aus Metallen und Legierungen (ISO 10993-15:2019)

This European Standard was approved by CEN on 19 April 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

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

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European foreword

This document (EN ISO 10993-15:2023) 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 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

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 10993-15:2009.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For the relationship with EU Directive(s) / Regulation(s), 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 10993-15:2019 has been approved by CEN as EN ISO 10993-15:2023 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), c) and h)	4, 6 and 7	10.1 a), b), c) and h) are only partly covered by ISO 10993-15, since the standard does not provide requirements on design and manufacture. However, this part of ISO 10993 provides considerations on how to plan a degradation study of metallic materials intended for use in medical devices in order to obtain quantitative degradation data as a basis for the safety evaluation of a medical device. Therefore, this standard provides a means to evaluate degradation risks associated with the metallic materials which are used. These tests are not intended to evaluate or determine the performance of the test sample in terms of mechanical or functional loading. For 10.1 a), flammability is not covered.

NOTE 4 This part of EN ISO 10993 refers to ISO 10993-1 which itself refers to ISO 14971. In Europe, it should be assumed that the reference to ISO 14971 is to EN ISO 14971:2019/A11:2021.

General Note: Presumption of conformity depends on also complying with the relevant parts of the ISO 10993 series.

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 3585	ISO 3585:1998	Borosilicate glass 3.3 - Properties	None For applicable standard edition see Column 2
ISO 3696	ISO 3696:1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696:1995
ISO 8044	ISO 8044:2020	Corrosion of metals and alloys - Vocabulary	EN ISO 8044:2020
ISO 10993-1	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1:	EN ISO 10993-1:2020

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
		Evaluation and testing within a risk management process	
ISO 10993-9	ISO 10993-9:2019	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	EN ISO 10993-9:2021
ISO 10993-12	ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
ISO 10993-13	ISO 10993-13:2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	EN ISO 10993-13:2010
ISO 10993-14	ISO 10993-14:2001	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	EN ISO 10993-14:2009
ISO 10993-16	ISO 10993-16:2017	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	EN ISO 10993-16:2017

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 10993-15

Second edition
2019-11

Biological evaluation of medical devices —

Part 15: Identification and quantification of degradation products from metals and alloys

Évaluation biologique des dispositifs médicaux —

Partie 15: Identification et quantification des produits de dégradation issus des métaux et alliages

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