SLOVENSKI STANDARD
SIST EN ISO 10993-18:2020/A1:2023

01-oktober-2023

Biološko ovrednotenje medicinskih pripomočkov - 18. del: Kemična opredelitev lastnosti materialov za medicinske pripomočke znotraj procesov obvladovanja tveganja - Dopolnilo A1: Določitev faktorja negotovosti (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 - Amendment 1: Determination of the uncertainty factor (ISO 10993-18:2020/Amd 1:2022)

Biologische Beurteilung von Medizinprodukten - Teil 18: Chemische Charakterisierung von Werkstoffen für Medizinprodukte im Rahmen eines Risikomanagementsystems - Änderung 1: Bestimmung des Unsicherheitsfaktors (ISO 10993-18:2020/Amd 1:2022)

Évaluation biologique des dispositifs médicaux - Partie 18: Caractérisation chimique des matériaux des dispositifs médicaux au sein d'un processus de gestion du risque - Amendement 1: Détermination du coefficient d'incertitude (ISO 10993-18:2020/Amd 1:2022)

Ta slovenski standard je istoveten z: **EN ISO 10993-18:2020/A1:2023**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-18:2020/A1:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-18:2020/A1

July 2023

ICS 11.100.20

English Version

Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor (ISO 10993-18:2020/Amd 1:2022)

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This amendment A1 modifies the European Standard EN ISO 10993-18:2020; it was approved by CEN on 30 April 2022.

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

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European foreword

This document (EN ISO 10993-18:2020/A1:2023) 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 Amendment to the European Standard EN ISO 10993-18:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 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 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 10993-18:2020/Amd 1:2022 has been approved by CEN as EN ISO 10993-18:2020/A1:2023 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 a Commission's standardization request 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 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) and h)	5 and 6	This standard provides requirements and recommendations for the chemical characterization of medical devices as part of a risk management process, including a qualitative characterization of the chemicals and materials used, a quantitative characterization of the amounts of chemicals and materials used and an evaluation of chemical release (leachable and extractable profile) in both the design and manufacturing processes. This chemical characterization can be used to define or confirm chemical specifications [10.1 h)] and evaluate the risk of toxicity [10.1 a) and b)] and biocompatibility [10.1 b)]. Flammability [10.1 a)] is not covered. For 10.1 b), ADME (absorption, distribution, metabolism, and excretion) is not covered. . For 10.1 h), physical specifications are not covered.
10.2	5 and 6	This standard provides requirements and recommendations for the chemical characterization of medical devices as part of a risk management process, including an evaluation of the release of contaminants and residues (composition, leachable and extractable profile) in both the design and manufacturing processes. Packaging is not covered. Aspects of contaminants and residues during transport and storage are not covered.
10.4.1 (First paragraph, first sentence)	5 and 6	This standard provides requirements and recommendations for the chemical characterization of medical devices as part of a risk management process, including an evaluation of chemical substances that may be released from the medical device (composition, leachable and extractable profile) in both the design and manufacturing processes. Particles and wear debris 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 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 10993-17	ISO 10993-17:2002	*Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*	EN ISO 10993-17:2009
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 10993-18

Second edition
2020-01

AMENDMENT 1
2022-05

Biological evaluation of medical devices —

Part 18: Chemical characterization of medical device materials within a risk management process

AMENDMENT 1: Determination of the uncertainty factor

Évaluation biologique des dispositifs médicaux —
Partie 18: Caractérisation chimique des matériaux des dispositifs médicaux au sein d'un processus de gestion du risque

AMENDEMENT 1: Détermination du coefficient d'incertitude

Reference number
ISO 10993-18:2020/Amd.1:2022(E)

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