საქართველოს სტანდარტი

სსკ: 11.100.20

სამედიცინო მოწყობილობების ბიოლოგიური შეფასება - ნაწილი 12: ნიმუშების მომზადება და ეტალონური (რეფერენსული) მასალები
(ისო 10993-12: 2021)

სსტ ენ ისო 10993-12:2021/2021

საინფორმაციო მონაცემები

1 მიღებულია და დაშვებულია სამოქმედოდ: სსიპ-საქართველოს სტანდარტებისა და მეტროლოგიის ეროვნული სააგენტოს გენერალური დირექტორის 01/11/2021 წლის № 64 განკარგულებით

2 მიღებულია „თავფურცლის“ თარგმნის მეთოდით: სტანდარტიზაციის ევროპული კომიტეტის სტანდარტი ენ ისო 10993-12:2021 ,, სამედიცინო მოწყობილობების ბიოლოგიური შეფასება - ნაწილი 12: ნიმუშების მომზადება და ეტალონური (რეფერენსული) მასალები (ისო 10993-12: 2021)”

3 პირველად

4 რეგისტრირებულია: სსიპ-საქართველოს სტანდარტებისა და მეტროლოგიის ეროვნული სააგენტოს რეესტრში: 01/11/2021 წლის №268-1.3-021606

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-12

June 2021

ICS 11.100.20

Supersedes EN ISO 10993-12:2012

English Version

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

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

Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien (ISO 10993-12:2021)

This European Standard was approved by CEN on 15 September 2020.

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, Turkey 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 E

Contents

Page

European foreword

This document (EN ISO 10993-12:2021) 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 December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.

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 10993-12:2012.

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

For the relationship with EU Directive(s) see informative Annex ZA, which is integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between undated normative references and dated EN and ISO standards

References as listed in the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 10993-1	EN ISO 10993-1:2020 [a]	ISO 10993-1:2018
ISO 10993-5	EN ISO 10993-5:2009	ISO 10993-5:2009
ISO 10993- 17	EN ISO 10993-17: 2009	ISO 10993-17:2002
ISO 10993-18	EN ISO 10993-18:2020 [a]	ISO 10993-18:2020
[a] Under preparation at European level.		

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10993-12:2021 has been approved by CEN as EN ISO 10993-12:2021 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 a Commission's standardisation request 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].

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 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.

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 This Annex ZA is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 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]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
10.2 (first sentence only)	4, 5, 6, 7, 8, 9, 10 and 11	10.2 *is only partly covered by this standard, since the standard does not provide requirements on design and manufacture and does not oblige to minimize risk.* *However, this standard provides a means of preparing samples to assess conformity with this part of this general health and safety requirment in conjunction with other relevant parts of* ISO 10993 *for the design and manufacture of medical devices. Packaging is not covered.* *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 standard, since the standard does not provide requirements on design and manufacture and does not oblige to minimize risk.* *However, this standard provides a means of preparing samples of medical devices to assess conformity with this part of this general health and safety requirment in conjunction with other relevant parts of* ISO 10993*.* *Other forms of toxicity are not dealt with in this standard.*

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

Biological evaluation of medical devices —

Part 12: Sample preparation and reference materials

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

Reference number
ISO 10993-12:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 fifth edition cancels and replaces the fourth edition (ISO 10993-12:2012), which has been technically revised.

The main changes compared to the previous edition are as follows:

— change of scope to cover extractions only for biological evaluation tests;

— harmonization of definitions with ISO 10993-18;

— revision of 10.3.1 extraction condition table and Annex D regarding exhaustive extraction.

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

It is important that sample preparation methods be appropriate for both the biological evaluation methods and the materials being evaluated. Each biological test method requires the selection of materials, extraction solvents and conditions.

This document is based on existing national and international standards and regulations, wherever possible.