ICS 11.100, 11.100.20 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2026

STN	**Biologické hodnotenie zdravotníckych pomôcok Časť 1: Požiadavky a všeobecné princípy na hodnotenie biologickej bezpečnosti v rámci procesu manažérstva rizika (ISO 10993-1: 2025)**	**STN EN ISO 10993-1** 85 6510

Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO 10993-1:2025)

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. 03/26

Obsahuje: EN ISO 10993-1:2025, ISO 10993-1:2025

Oznámením tejto normy sa ruší
STN EN ISO 10993-1 (85 6510) z júna 2021

142120

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-1

December 2025

ICS 11.100; 11.100.20

Supersedes EN ISO 10993-1:2020

English Version

Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO 10993-1:2025)

Évaluation biologique des dispositifs médicaux - Partie 1: Exigences et principes généraux pour l'évaluation de la sécurité biologique au sein d'un processus de gestion des risques (ISO 10993-1:2025)

Biologische Beurteilung von Medizinprodukten - Teil 1: Anforderungen und allgemeine Grundsätze für die Beurteilung der biologischen Sicherheit im Rahmen eines Risikomanagementsystems (ISO 10993-1:2025)

This European Standard was approved by CEN on 18 August 2025.

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 10993-1:2025 E

Contents

Page

European foreword

This document (EN ISO 10993-1:2025) 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 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of an identical text or by endorsement, at the latest by June 2026, and conflicting national standards shall be withdrawn at the latest by June 2026.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 10993-1:2020.

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 10993-1:2025 has been approved by CEN as EN ISO 10993-1:2025 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.

NOTE 4 General Safety and Performance Requirements listed in Table ZA.1 are specific to biological safety for patients only, unless the medical device is used for personal protection of the user

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)	4.1, 4.3, 6.2, 6.3, 6.5, 7, 8, 10	This is partly covered by this document since the standard does not provide requirements for performance. Flammability is not covered.
10.1. b), d) and g)	4.1, 4.3, 5, 6.1, 6.2, 6.3, 6.4, 6.5, 7, 10	These are partly covered by this document since the standard does not provide requirements for performance.
10.2	4.1, 4.3, 5, 6.1, 6.2, 6.3, 6.4, 6.5, 7, 8, 10	Persons involved in the transport, storage and use of medical devices are not covered unless the user is the patient, or the medical device is used for personal protection.
10.4.1 (first paragraph)	4.1, 4.3, 5, 6.1, 6.2, 6.3, 6.4, 6.5, 7, 8, 10	
10.6	4.1, 4.3, 6.2, 6.3, 6.5, 7, 8, 10	

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 10993-2	ISO 10993-2:2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements	EN ISO 10993-2:2022
ISO 10993-3	ISO 10993-3:2014 ISO 10993-3:2014/AMD 1:2025	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014 EN ISO 10993-4:2017/A1:2025
ISO 10993-4	ISO 10993-4:2017	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
ISO 10993-5	ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009 EN ISO 10993-5:2009/A11:2025

ISO 10993-6	ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	EN ISO 10993-6:2016
ISO 10993-7	ISO 10993-7: 2008 ISO 10993-7: 2008/AMD 1: 2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7: 2008 EN ISO 10993-7: 2008/A1 2022
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 10993-10	ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization	EN ISO 10993-10:2023
ISO 10993-11	ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	EN ISO 10993-11:2018
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 10993-15	ISO 10993-15:2019	Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys	EN ISO 10993-15:2023
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
ISO 10993-17	ISO 10993-17:2023	Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents	EN ISO 10993-17:2023
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/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/TS 10993-20	ISO/TS 10993-20:2006	Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices	For applicable standard edition see Column 2
ISO 10993-23	ISO 10993-23:2021 ISO 10993-23:2021/AMD 1:2025	Biological evaluation of medical devices — Part 23: Tests for irritation	EN ISO 10993-23:2021 EN ISO 10993-23:2021/A1:2025
ISO 14971:2019	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.

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**
Intended use	3.23	Article 2 (12)	The definition is substantially equivalent. The definition in this document specifies that the specifications, instructions, and information provided by the manufacturer, are all elements of the intended use. This text aligns with the definition in the Regulation as detailed in the brackets below: The Regulation refers to data supplied by the manufacturer on the label (information), in the instructions for use (instructions) or in promotional or sales materials (information) or statements and as specified by the manufacturer in the clinical evaluation (specifications). The definition in the Regulation does not require additional information beyond what is considered in the definition in this standard.
Medical device	3.28	Article 2 (1)	Both definitions are substantially equivalent. In the Regulation, the definition also specifies: • Under medical purposes, the Regulation adds

			in the first bullet point prediction and prognosis, • The third bullet point adds pathological process or state, • The fourth bullet has additional specification including organ, blood and *tissue* donations • A *medical device* can be a product used for cleaning and sterilisation of a *medical device* In this standard, the definition and Note 1 also specifies: • In the initial paragraph, the standard adds implement, machine, • In the initial paragraph, the standard specifies 'reagent' for invitro use, • The third bullet point adds 'support' of anatomy • A new bullet point added; supporting or sustaining life, • A bullet point added to note, *devices* (3.28) incorporating animal or human *tissues* (3.40); The review of the differences between the Regulation and standard as detailed above concluded that the concept of each of the differences were already addressed by text in the other definition. Therefore, all terms within the definition in the Regulation are covered.
Nanomaterial	3.30	Article 2 (18)	ISO 10993-1 definition only describes materials with nanoscale dimensions or structures without considering their regulatory implications. The nanoscale definition is the same as detailed in the Regulation i.e. 1-100nm. The Regulation further qualifies nanomaterials as a material which contains 50% or more particles with external dimensions within the nanoscale, while the definition in this standard focuses on the attributes of nanoparticles within a material. For the purpose of biological evaluation, the presence and safety of nanoparticles needs to be assessed, irrespective of the material falling within the nanomaterial definition in the Regulation or not.
User	3.43	Article 2 (37)	Both definitions are substantially equivalent.

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 10993-1

Sixth edition
2025-11

Biological evaluation of medical devices —

Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process

Évaluation biologique des dispositifs médicaux —

Partie 1: Exigences et principes généraux pour l'évaluation de la sécurité biologique au sein d'un processus de gestion des risques

Reference number
ISO 10993-1:2025(en)

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 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 sixth edition cancels and replaces the fifth edition (ISO 10993-1:2018), which has been technically revised.

The main changes are as follows:

— this document has been completely reorganised and the title has been aligned with the risk management framework described in ISO 14971;

— content has been added to provide guidance and clarification of calculation of exposure duration;

— content has been added to provide guidance on characterization of the device and identification of biological hazards;

— the identification of biological effects (previously referred to as biological end points) has been modified;

— the term “externally communicating” has been replaced by language which reflects the specific tissue contact of device components;

— the term “effects after implantation” has been changed to “local effects after tissue contact” as some non-implanted devices also will need this type of assessment;

— Annex A has been revised to move most of the content to the main text and the remaining text in Annex A is now confined to the provision of guidance on materials characterization;

— Annex B has been added to explain the rationale for the changes to biological effects listed in Table 1 to Table 4.

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

The aim of this document is to provide guidance and requirements for the biological evaluation of a medical device within a risk management process to protect humans from biological risks arising from the use of medical devices and the materials from which they are made. Biological risk evaluation compares the estimated biological risk against given risk criteria to determine the acceptability of the biological risk as part of the overall risk management.

Biological evaluation is primarily concerned with medical device biological safety, through consideration of risks associated with biological hazards. Nonetheless, some activities undertaken in the course of biological evaluation in addition to assessments of long-term safety can also generate information on device performance. For example, functional implant models can be used to assess long-term responses such as tissue ingrowth. Biological evaluation, as described in this document, is synonymous with biocompatibility evaluation.

Biological evaluation is conducted on the finished medical device. The principles and methods described can also be useful in the evaluation of candidate materials or prototype devices during a medical device development process, and data obtained from such evaluations can be of value in the assessment of the finished medical device.

Medical device design is wide-ranging, and, at one extreme, a medical device consists only of a single material, which can exist in more than one physical form, while at the other extreme, is a complex article consisting of numerous components made from multiple materials. Biological safety cannot be considered in isolation from the overall medical device design and can require the balancing of conflicting requirements. For example, the choice of the best material with respect to its biological safety can result in a less functional medical device.

The evaluation of biological safety is conducted in the context of the intended use of a particular medical device. Materials can be safe in one medical device and not in another. It is impossible to make generalized conclusions about the safety of a particular material for all medical applications. Biological responses that are regarded as adverse, caused by a material in one application, are not necessarily regarded as adverse in a different situation.

Physical and chemical information supports the overall biological evaluation and can be used to inform testing needs, if any. When biological testing is required, such testing is based upon in vitro, ex vivo or in vivo models. The interpretation of the results of biological tests requires caution because the inherent variability in biological responses between species and individuals means that the biological response observed in animal or cell culture models can differ from those observed in clinical use. Differences in response to the same material among individuals means that some individuals can have adverse reactions, even to well-established materials. Thus, biological evaluation is an exercise in risk management. When applied to the evaluation of candidate materials or prototype devices during a medical device development process, biological evaluation allows the informed and timely consideration of risk control measures such as use of alternative materials, manufacturing processes or designs.

The biological evaluation process described in this document draw on all available sources of information relevant to biological safety of the medical device, including post-market information. This approach allows a comprehensive review of the medical device, the identification of biological hazards and the biological harms which can arise and estimation of the associated risks. This comprehensive approach allows for the identification of any gaps in the existing data set and the consequent need for supplementary assessments (e.g. chemical analysis and hazard identification, biological testing to refine a biological risk estimate) to be conducted.

This document is supported by a wide range of test methods and guidance published in other documents in the ISO 10993 series, as well as other standards. Those who use this document can also consider more specific guidance contained in device-specific standards, where available. For some complex or novel materials or technologies, it can be difficult to use the established methods described in the ISO 10993 series. This document allows for the use of alternative procedures where scientifically justified.

The welfare of animals is very important and the selection of test methods and evolution of testing within the ISO 10993 framework is directed to continue to reduce, refine and, where possible, replace the use of animals for biological testing.

International Standard **ISO 10993-1:2025(en)**

Biological evaluation of medical devices —

Part 1:
Requirements and general principles for the evaluation of biological safety within a risk management process

1 Scope

This document specifies the requirements and general principles governing the biological evaluation of medical devices within a risk management process according to ISO 14971.

This document applies to the biological evaluation of medical devices that have direct contact or indirect contact with either:

— a patient's body during intended use or reasonably foreseeable misuse; or

— the body of other users who are not patients, if the medical device is intended for personal protection (e.g. medical gloves, surgical masks).

Biological evaluation assesses the biological safety of the medical device by considering the biological risks associated with:

— constituents of a medical device; and

— tissue-device interactions (including physical effects).

The biological evaluation specified in this document can address the biological safety of the medical device, considering the life cycle from design and development through initial use of the finished medical device to final decommissioning or withdrawal from use. The biological evaluation considers both the biological safety of the finished device in first use, and the significance of any changes to the medical device which can occur throughout the life cycle. However, the evaluation of risks related to environmental impacts of decommissioning of medical devices are not within the scope of this document. This document does not mandate re-testing of medical devices that are already on the market and have established and acceptable safety profiles (see 6.6.2).

This document can be useful to support clinical or usability evaluations of medical devices. For example, a biological evaluation is a pre-requisite for conducting a clinical trial. This means that principles outlined in this document can be applied to the evaluation of prototype or development stage devices, as well as to finished medical devices.

Other parts of the ISO 10993 series cover specific aspects of biological evaluation, such as chemical characterization, biological testing, sample preparation, animal welfare and toxicological risk assessment.

For some types of medical devices, specific requirements from other standards (outside the ISO 10993 series) can be considered with a justification for the approach taken if there are differences between the requirements of the ISO 10993 series and those provided in other standards. For example, the ISO 18562 series provides specific requirements for biological evaluation of breathing gas pathway medical devices and ISO 7405 provides specific requirements for biological evaluation of dental devices.

The evaluation of risks related to infectious agents [e.g. bacteria, moulds, yeasts, viruses, transmissible spongiform encephalopathy (TSE) agents] is not within the scope of this document.

NOTE 1 The evaluation of bacterial endotoxins is addressed by ISO 11737-3.

NOTE 2 The evaluation of risks related to viruses, TSE agents and other pathogens originating from materials of animal origin is addressed by the ISO 22442 series.

2 Normative references

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 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-9:2019, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for skin sensitization*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 10993-13, *Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices*

ISO 10993-14, *Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics*

ISO 10993-15, *Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys*

ISO 10993-16, *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables*

ISO 10993-17:2023, *Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents*

ISO 10993-18:2020, *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 10993-23, *Biological evaluation of medical devices — Part 23: Tests for irritation*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*