SLOVENSKI STANDARD
SIST EN ISO 10993-2:2023

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Nadomešča:
SIST EN ISO 10993-2:2006

Biološko ovrednotenje medicinskih pripomočkov - 2. del: Zahteve za varstvo živali (ISO 10993-2:2022)

Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2022)

Biologische Beurteilung von Medizinprodukten - Teil 2: Tierschutzbestimmungen (ISO 10993-2:2022)

Évaluation biologique des dispositifs médicaux - Partie 2: Exigences relatives à la protection des animaux (ISO 10993-2:2022)

Ta slovenski standard je istoveten z: **EN ISO 10993-2:2022**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-2:2023 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-2

November 2022

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Supersedes EN ISO 10993-2:2006

English Version

Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2022)

Évaluation biologique des dispositifs médicaux - Partie 2: Exigences relatives à la protection des animaux (ISO 10993-2:2022)

Biologische Beurteilung von Medizinprodukten - Teil 2: Tierschutzbestimmungen (ISO 10993-2:2022)

This European Standard was approved by CEN on 30 October 2022.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 10993-2:2022 E

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European foreword

This document (EN ISO 10993-2:2022) 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 May 2023, and conflicting national standards shall be withdrawn at the latest by May 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 10993-2:2006.

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 10993-2:2022 has been approved by CEN as EN ISO 10993-2:2022 without any modification.

INTERNATIONAL STANDARD

ISO 10993-2

Third edition
2022-11

Biological evaluation of medical devices —

Part 2: Animal welfare requirements

Évaluation biologique des dispositifs médicaux —
Partie 2: Exigences relatives à la protection des animaux

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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).

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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, *Biocompatibility of medical and dental materials and devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10993-2:2006), which has been technically revised.

The main changes are as follows:

— laboratory animal veterinarian and their responsibilities and authority have been clarified;

— requirements for trained veterinary care staff have been added;

— ILAR Guide, IACLAM and AAALAC International have been added;

— aseptic methods, monitoring, pharmaceutical grade of chemical usage for surgery have been added.

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 goal of the ISO 10993 series is the protection of humans in the context of the use of medical devices.

This document supports the goal of the ISO 10993 series by promoting good science through paying proper regard to maximizing the use of scientifically sound non-animal tests and by ensuring that those animal tests performed to evaluate the biological properties of materials used in medical devices are conducted humanely according to recognized ethical and scientific principles.

The application of such humane experimental techniques, including high standards of animal care and accommodation, both help to ensure the scientific validity of safety testing and enhance the welfare of the animals used.