SLOVENSKI STANDARD
oSIST prEN ISO 10993-2:2020

01-april-2020

Biološko ovrednotenje medicinskih pripomočkov - 2. del: Zahteve za varstvo živali (ISO/DIS 10993-2:2020)

Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO/DIS 10993-2:2020)

Biologische Beurteilung von Medizinprodukten - Teil 2: Tierschutzbestimmungen (ISO/DIS 10993-2:2020)

Évaluation biologique des dispositifs médicaux - Partie 2: Exigences relatives à la protection des animaux (ISO/DIS 10993-2:2020)

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

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

oSIST prEN ISO 10993-2:2020 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 10993-2

ISO/TC **194**

Secretariat: **DIN**

Voting begins on:
2020-02-13

Voting terminates on:
2020-05-07

Biological evaluation of medical devices —

Part 2:
Animal welfare requirements

Évaluation biologique des dispositifs médicaux —

Partie 2: Exigences relatives à la protection des animaux

ICS: 11.100.20

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 10993-2:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
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.

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

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

Addition of veterinary care:

— clarification on laboratory animal veterinarian and their responsibilities and authority;

— requirements for trained veterinary care staff;

— addition of ILAR Guide, IACLAM and AAALAC International

— addition of aseptic methods, monitoring, pharmaceutical grade of chemical usage for surgery;

— usage of other analgesics than NSAIDs;

— other alternatives such as TTC are mentioned.

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 of International Standards 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, and mimimizing pain and distress to ensure the scientific validity of safety testing and enhance the welfare of the animals used.

Biological evaluation of medical devices —

Part 2:
Animal welfare requirements

1 Scope

This document specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made to minimize pain and distress, which can negatively affect the validity of the data. This document is for those who commission, design and perform testing or evaluate the data to assess the biocompatibility of materials intended for use in medical devices, or that of the medical devices themselves.

This document makes recommendations and offers guidance intended to facilitate further reductions in the overall number of animals used, refinement of test methods to reduce or eliminate pain or distress in animals, and the replacement of animal tests by other scientifically valid means not requiring animal tests.

This document applies to tests performed on living vertebrate animals, other than man, to establish the biocompatibility of materials or medical devices.

This document does not apply to tests performed on invertebrate animals and other lower forms; nor (other than with respect to provisions relating to species, source, health status, and care and accommodation) does it apply to testing performed on isolated tissues and organs taken from vertebrate animals that have been euthanized.

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 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1:2018 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
acclimatization
some period following transportation of animal to restore homeostasis and physiological measures return to normal

Note 1 to entry: 7 days may be appropriate for most cases.

3.2
alternative method
any test method that replaces an animal test, reduces the numbers of animals used, or refines the procedures applied

3.3
animal
any live non-human vertebrate, including immature forms during gestation where the ability to sense pain is known

3.4
animal test
experimental use of animals for medical and scientific purposes

Note 1 to entry: The definition of an animal test excludes acts of recognized veterinary practice applied for the benefit of an animal or the group of animals of which it is part; recognized husbandry practices to manage or conserve the animal or the group of which it is part; marking by methods which cause no more than momentary pain or distress; and euthanasia.

Note 2 to entry: The prevention of pain, suffering, distress or lasting harm by the effective use of anaesthesia or analgesia or other methods of rendering the animal insentient to pain (e.g. decerebration) does not place animal tests outside the scope of this definition. The administration of anaesthetics, analgesics or other methods of rendering the animal insentient to pain are considered to constitute an integral part of the animal test.

3.5
competent authority
body designated or recognized by a national government to take responsibility for overseeing, supervising or regulating animal tests, or the breeding and supply of purpose-bred animals for use on such tests, within the scope of this document

3.6
euthanasia
humane killing of an animal by a method causing a minimum of physical and mental suffering

3.7
humane endpoints
pre-determined, specific criteria and measures to be implemented to minimize or terminate pain, suffering or distress caused by animal tests as soon as

— the scientific objectives have been met, or

— it is realized that the scientific endpoints cannot be met, or

— the animal welfare problems being encountered are greater than can be justified by the importance, potential benefits, objectives and nature of the study

3.8
laboratory animal veterinarian (qualified)
person qualified and responsible for the health and wellbeing of all laboratory animals at the institution through certification in their specialty by training, experience, research, and publication, and a demonstrable knowledge and skill

Note 1 to entry: There is an International Association of Colleges of Laboratory Animal Medicine (IACLAM) that is an association of associations, specifically the member Colleges of laboratory animal medicine. Each college has members that, in addition to their demonstrated proficiency in laboratory animal medicine, also possess subspecialization in a variety of areas that have direct bearing on the care, use and welfare of laboratory animals.

3.9
procedural training
prior training and acclimatizing of animals to the interventions to be performed during an animal test, with a view to minimizing stress to the animal when animal tests are conducted

3.10
protocol
documentation prepared in advance of animal tests being undertaken setting out the justification, rationale and test method (including scientific and humane endpoints) for the animal tests

3.11
purpose-bred animal
animal bred with the intention that it be used in animal tests or for other experimental or scientific purposes

3.12
reduction
methods which minimize the number of animals used in an animal test to meet a defined scientific objective

3.13
refinement
sum total of measures taken to safeguard the welfare of the test animals by minimizing any resulting pain, suffering, distress or lasting harm to the animals that are used

3.14
replacement
scientifically valid, reasonably and practically available test method that either completely or partially replaces the use of living vertebrate animals with test methods that do not have the potential to cause pain or distress to animals

3.15
Specific Pathogen Free (SPF) animal
animal that are free of defined pathogens

3.16
test animal
animal used *in vivo* tests, or used to provide tissue for *ex vivo* or *in vitro* tests

3.17
validation
formal process by which the reliability and relevance of a test method is established for a particular purpose

3.18
veterinary care
promoting an animal's health and welfare before, during and after animal procedures and providing advice and guidance based on best practice.

4 Requirements

4.1 General

This document sets forth essential requirements when animal tests are being considered, planned or performed for the biological evaluation of materials and medical devices.

It has been developed to protect the welfare of animals used in the biological evaluation of materials used in medical devices without compromising, indeed to help to ensure, the scientific validity of the test results and the risk assessments that shall subsequently be performed.

This document focuses on the need to demonstrate that animal welfare is properly considered when expert judgement has to be exercised in relation to the biological evaluation of medical device materials, and that the principles of humane experimental technique are demonstrably applied to the design and conduct of animal tests.