SLOVENSKI STANDARD
SIST EN ISO 7199:2024

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Nadomešča:
SIST EN ISO 7199:2017
SIST EN ISO 7199:2017/A1:2020

Vsadki (implantati) za srce in ožilje ter umetni organi - Izmenjevalniki krvnih plinov (oksigenatorji) (ISO 7199:2024)

Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) (ISO 7199:2024)

Kardiovaskuläre Implantate und künstliche Organe - Blut-Gas-Austauscher (Oxygenatoren) (ISO 7199:2024)

Implants cardiovasculaires et organes artificiels - Échangeurs gaz/sang (oxygénateurs) (ISO 7199:2024)

Ta slovenski standard je istoveten z: **EN ISO 7199:2024**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN ISO 7199:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7199

September 2024

ICS 11.040.40

Supersedes EN ISO 7199:2017

English Version

Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) (ISO 7199:2024)

Implants cardiovasculaires et organes artificiels - Échangeurs gaz/sang (oxygénateurs) (ISO 7199:2024)

Kardiovaskuläre Implantate und künstliche Organe - Blut-Gas-Austauscher (Oxygenatoren) (ISO 7199:2024)

This European Standard was approved by CEN on 10 August 2024.

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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 7199:2024) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 205 “Non-active 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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.

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 7199:2017.

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.

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Endorsement notice

The text of ISO 7199:2024 has been approved by CEN as EN ISO 7199:2024 without any modification.

International Standard

ISO 7199

Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

Implants cardiovasculaires et organes artificiels — Échangeurs gaz/sang (oxygénateurs)

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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 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).

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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 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7199:2016), which has been technically revised. It also incorporates the Amendment ISO 7199:2016/Amd.1:2020.

The main changes are as follows:

— circular definitions have been corrected for platelet reduction (3.10), plasma free haemoglobin (3.11) and white blood cell reduction (3.12);

— the definition of priming volume (3.18) has been added;

— the sampling time point of 5 min has been deleted in Table 2.

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

This document is intended to ensure that devices designed to affect the exchange of gases in support of, or as a substitution for, the normal respiratory function of the lungs have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This document therefore contains procedures to be used for the evaluation of extracorporeal blood-gas exchangers (oxygenators). Type test procedures to determine the gas transfer, blood cell damage and heat exchanger performance are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of an oxygenator that suits the needs of the patient.

This document also includes minimum reporting requirements that allow the user to compare performance characteristics of oxygenators of different designs in a standard way.

This document makes reference to other International Standards in which methods for the determination of characteristics common to medical devices can be found.

No provisions have been made for the quantification of microbubble generation or for the non-formed elements of bovine blood because there currently is no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this document.

This document contains only those requirements that are specific to oxygenators. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.