SÜDAME-VERESOONKONNA IMPLANTAADID JA TEHISORGANID. VERE GAASIVAHETID (OKSÜGENERAATORID)

Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) (ISO 7199:2016)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 7199:2017 sisaldab Euroopa standardi EN ISO 7199:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7199:2017 consists of the English text of the European standard EN ISO 7199:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 25.01.2017.	Date of Availability of the European standard is 25.01.2017.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) (ISO 7199:2016)

Implants cardiovasculaires et organes artificiels - Échangeurs gaz/sang extracorporels (oxygénateurs) (ISO 7199:2016)

Kardiovaskuläre Implantate und künstliche Organe - Blutgasaustauscher (Oxygenatoren) (ISO 7199:2016)

This European Standard was approved by CEN on 6 November 2016.

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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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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 7199:2017) 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 July 2017, and conflicting national standards shall be withdrawn at the latest by July 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7199:2014.

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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 and Amd 1:2006
ISO 10993-7	EN ISO 10993-7:2008 and EN ISO 10993-7:2008/AC:2009	ISO 10993-7:2008 and ISO 10993-7:1/Cor 1:2009
ISO 10993-11	EN ISO 10993-11:2009	ISO 10993-11:2006
ISO 11135	EN ISO 11135:2014	ISO 11135:2014
ISO 11137-1	EN ISO 11137-1:2006 and EN ISO 11137-1:2006/A1:2013	ISO 11137-1:2006 and Amd 1:2013
ISO 11607-1	EN ISO 11607-1:2009 and EN ISO 11607-1:2009/A1:2014	ISO 11607-1:2006 and Amd 1:2014
ISO 11607-2	EN ISO 11607-2:2006 and EN ISO 11607-2:2006/A1:2014	ISO 11607-2:2006 and Amd 1:2014
ISO 15675	—	ISO 15675:2009
ISO 17665-1	EN ISO 17665-1:2006	ISO 17665-1:2006

Endorsement notice

The text of ISO 7199:2016 has been approved by CEN as EN ISO 7199:2017 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request *'M/023 concerning the development of European standards related to medical devices'* to provide a voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 essential requirements of that Directive, 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 Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

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 an Essential 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 Directive 93/42/EEC [OJ L 169]

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.2	4.1.1; 4.1.2; 5.2; 5.2.1; 5.2.2; 5.3; 5.3.1; 5.3.1.1; 5.3.1.2; 5.3.2; 5.3.2.1; 5.3.2.2; 6.2.1 d); 6.2.2 d); 6.3 u) 1)	4.1.1 and 4.1.2 address manufacturers' requirements to ensure product sterility, non-pyrogenicity, and biocompatibility. 5.2 and 5.3 with associated sub-clauses address testing for the above to verify compliance that products are sterile, non-pyrogenic, and biocompatible. 6.2.1, 6.2.2 and 6.3 with associated sub-clauses address labelling to include the manufacturers' documentation attesting to

		the above, which are to be supplied on the unit container, shipping container, and accompanying product literature, including «Instructions for Use».
7.3	4.3.6; 4.3.6.1; 4.3.6.2; 5.2; 5.2.1; 5.2.2; 5.4.3; 5.4.3.1; 5.4.3.2	4.3.6 with associated sub-clauses address blood cell damage when the product is used for its intended purpose. 5.2 with associated sub-clauses address biological characteristics and manufacturers' compliance for verification regarding sterility, non-pyrogenicity and biocompatibility. 5.4.3 with associated sub-clauses describe specific testing parameters for documenting blood cell damage. The second part of ER 7.3 relating to medicinal products is not covered.
7.5	4.2.1; 4.2.2; 4.2.4	4.2.1 and 4.2.2 address minimizing the risk of leakage by the requirement that blood pathways (e.g. oxygenator, heat exchanger) do not leak. 4.2.4 addresses the requirement that connectors used for connections to the blood pathways must be secure, which also addresses the minimization of risk of leakage. Only the first sentence of ER 7.5 is covered.
8.1	4.1.1; 4.1.2; 6.2.1 d); 6.2.2 d); 6.3 u) 1)	4.1.1 and 4.1.2 require products to be sterile, non-pyrogenetic, and biocompatible. 6.2.1, 6.2.2, and 6.3 with associated sub-clauses address sterilization information to be supplied on labelling for the units, shipping containers, and in the accompanying «Instructions for Use». Only the first sentence of ER

		8.1 is covered.
9.1	4.2.4	4.2.4 addresses manufacturers‘ requirements that connectors provide for secure connection of additional products for assembly into a system for its intended use. 4.2.4 covers ER 9.1 in respect of blood pathway connections only.
13.1	6.1 a); 6.2.1 a) h); 6.2.2 a); 6.3 a)	6.1, 6.2 and 6.3 with associated sub-clauses address the manufacturers’ identification, «Instructions for Use» for the safe use of the product and any special handling or storage conditions. 13.1, first paragraph, last five words only are covered by 6.1 a), 6.2.1 a), 6.2.2 a) and 6.3 a) only.
13.2	6.2.1 g) i)	Clause 6.2.1 with associated sub-clauses address use of approved symbols on the unit container. 13.2 is covered only is respect of 'Read Instructions for use' and 'Single use only'.
13.3 a)	6.2.1 a), 6.2.2 a) and 6.3 a)	The standard does not address a requirement regarding an authorised representative when the manufacturer does not have a registered place of business in the Community. ER 13.3 a) is covered by 6.2.1 a), 6.2.2 a) and 6.3 a) but only in respect of manufacturer.
13.3 b)	6.2.1 b)-c); 6.2.2 b)-c); 6.3 b)	6.2.1, 6.2.2 and 6.3 with associated sub-clauses address identification of the device and contents of the packaging.
13.3 c)	6.2.1 d); 6.2.2 d)	6.2.1 and 6.2.2 with associated sub-clauses address designation of the sterility of the product on the

		unit and shipping containers and in the «Instructions for Use».
13.3 d)	6.2.1 f)	6.2.1 with the associated sub-clause address product batch, lot or serial number designations. ER 13.3 d) is only met if the batch code is preceded by the word 'LOT'.
13.3 e)	6.2.2 e)	6.2.2 with the associated sub-clause address expiry date on the unit container. ER 13.3 e) is only met if the expiry date is given as a year and month.
13.3 f)	6.2.1 i)	6.2.1 with the associated sub-clause address one-time (single) use of the device.
13.3 i)	6.2.1 h); 6.2.2 f)	6.2.1 and 6.2.2 with associated sub-clauses address labelling on the unit and shipping containers regarding any special handling or storage conditions.
13.3 j)	6.3 d)	6.3 and 6.4 with associated sub-clauses address special or unique procedures and limitations during use in accompanying documents. ER 13.3 j) is covered by 6.3 d) only in respect of the „Instructions for Use».
13.3 k)	6.2.1 g)	6.2.1 with the associated sub-clause address «Instructions for Use» containing warnings and precautions. ER 13.3 k) is covered by 6.2.1 g) only in respect of the unit container.
13.4	6.2.1 g); 6.3	6.2.1 with the associated sub-clause and 6.3 address «Instructions for Use» labelling on the unit container and in accompanying documents supplied with the product.

13.6 c)	6.3 e)-g)	6.3 with associated sub-clauses address mounting and connection of device components for safe use. ER 13.6 c) is covered only to the extent shown in 6.3 e)-g).
13.6 i)	6.3 e) f)	The standard addresses sterile products that do not require further treatment before use. 6.3 with associated sub-clauses address mounting of the device and assembly with other products before use. ER 13.6 i) is covered only to the extent shown in 6.3 e)-f).
13.6 p)	4.2.3	4.2.3 addresses testing of volumetric measurements and tolerances specified by the manufacturer. ER 13.6 p) is only covered for blood volumes only and only when the degree of accuracy is given in the „Instructions for Use».

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.

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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. 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. 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 on 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 the following URL: http://www.iso.org/iso/foreword.html

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO 7199:2009), which has been technically revised.

It also incorporates the Amendment ISO 7199:2009/Amd.1:2012.

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 evaluation of extracorporeal blood-gas exchangers (oxygenators). Type test procedures for determination of 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 will suit the needs of the patient.

This document also includes minimum reporting requirements, which will 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 determination of characteristics common to medical devices can be found.

No provisions have been made for quantification of microbubble generation or for 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. Such studies may be parts of a manufacturer's quality system.

This document contains only those requirements that are specific to oxygenators. Non-specific requirements are covered by references to other International Standards listed in the normative references clause. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.

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

1 Scope

This document specifies requirements for sterile, single-use, extracorporeal blood-gas exchangers (oxygenators) intended for supply of oxygen to, and removal of carbon dioxide from, the blood of humans.

This document also applies to heat exchangers and arterial filters that are integral parts of the oxygenator.

This document also applies to external equipment unique to the use of the oxygenator.

This document does not apply to

— implanted oxygenators,

— liquid oxygenators,

— extracorporeal circuits (blood tubing),

— separate heat exchangers,

— separate ancillary devices, and

— separate arterial line filter.

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

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

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

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

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 15675, *Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters*