ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 7199:2017

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

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

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

01/2017

National Foreword

This European Standard EN ISO 7199:2017 was adopted as Luxembourgish Standard ILNAS-EN ISO 7199:2017.

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- Participate in the design of standards
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7199

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English Version

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

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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