

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

ICS 11.040.40

National foreword

This British Standard is the UK implementation of EN ISO 7199:2014. It is identical to ISO 7199:2009, incorporating amendment 1:2012. It supersedes BS EN 12022:1999 and BS ISO 7199:2009+A1:2012, which are withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/2, Cardiovascular implants.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

The publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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30 April 2012	Implementation of ISO amendment 1:2012
31 December 2014	This corrigendum renumbers BS ISO 7199:2009+A1:2012 as BS EN ISO 7199:2014

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EN ISO 7199

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Supersedes EN 12022:1999

English Version

Cardiovascular implants and artificial organs - Blood-gas
exchangers (oxygenators) (ISO 7199:2009 + Amd 1:2012)

Implants cardiovasculaires et organes artificiels -
Échangeurs gaz/sang extracorporels (oxygénateurs) (ISO
7199:2009 + Amd 1:2012)

Kardiovaskuläre Implantate und künstliche Organe -
Blutgasaustauscher (Oxygenatoren) (ISO 7199:2009 + Amd
1:2012)

This European Standard was approved by CEN on 17 July 2014.

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Foreword

The text of ISO 7199:2009 + Amd 1:2012 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 7199:2014 by 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of an identical text or by endorsement, at the latest by February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

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 12022:1999.

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(s).

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

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Endorsement notice

The text of ISO 7199:2009 + Amd 1:2012 has been approved by CEN as EN ISO 7199:2014 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1.1; 4.1.2; 5.2; 6.2.1; 6.2.2; 6.3	7.2	Some redundancies, but all these EN sections address performance and sterility issues.
4.3.3; 5.2; 5.4.3	7.3	
4.2.1; 4.2.2; 4.2.4	7.5	
4.1.1; 6.2.1; 6.2.2; 6.3	8.1	
6.2.1; 6.2.2; 6.3	8.3	
6.2.1; 6.2.2; 6.3	8.4	
4.1.1; 5.2.1; 6.2.1; 6.2.2; 6.2.3	8.5	
6.2.1	8.6	
6.1; 6.2.1	8.7	
4.2.4	9.1	
6.1; 6.2; 6.3	13	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Introduction

This International Standard 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 labeling the device.

This International Standard 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 International Standard also includes minimum reporting requirements, which will allow the user to compare performance characteristics of oxygenators of different designs in a standard way.

This International Standard 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 International Standard. Such studies may be parts of a manufacturer's quality system.

This International Standard 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 section. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this International Standard does not cover non-toxicity.