Ekstrakorporale systemer til rensning af blod – Del 2: Ekstrakorporalt blodkredsløb ved hæmodialyse, hæmodiafiltrering og hæmofiltrering

Extracorporeal systems for blood purification – Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (ISO 8637-2:2018)

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ICS: 11.040.40

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IDT med: EN ISO 8637-2:2018

DS-publikationen er på engelsk.

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- **MOD:** Når publikationen er modificeret i forhold til en given publikation.

EUROPEAN STANDARD EN ISO 8637-2

NORME EUROPÉENNE

EUROPÄISCHE NORM August 2018

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English Version

Extracorporeal systems for blood purification - Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (ISO 8637-2:2018)

Systèmes extracorporels pour la purification du sang - Partie 2: Circuit sanguin extracorporel pour les hémodialyseurs, les hémodiafiltres et les hémofiltres (ISO 8637-2:2018)

Kardiovaskuläre Implantate und extrakorporale Système - Teil 2: Extrakorporaler Blutkreislauf bei Hämodialysatoren, Hämodiafiltern und Hämofiltern (ISO 8637-2:2018)

This European Standard was approved by CEN on 17 June 2018.

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

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

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European foreword

This document (EN ISO 8637-2:2018) 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 February 2019, and conflicting national standards shall be withdrawn at the latest by August 2021.

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 8638:2014.

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(s).

For the relationship with EU Directive(s) 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.

Endorsement notice

The text of ISO 8637-2:2018 has been approved by CEN as EN ISO 8637-2:2018 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 standardisation request M/023 concerning the development of European standards related to medical devices to provide one 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 thatDirective, 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 European Standard	Qualifying remarks/Notes
7.1	4.1, 4.2, 4.3, 5.2, 5.3, 5.4	
7.2	4.1, 4.2, 4.3, 5.2, 5.3, 5.4	Clauses 4.1 and 5.2, cover ER 7.2 in relation to Biological safety only. Clauses 4.2 and 5.3, cover ER 7.2 in relation to sterility only. Clauses 4.3 and 5.4, cover ER 7.2 in relation to Non-pyrogenenicity only.
7.3		Not applicable
7.4		Not applicable
7.5	5.2, 5.5	Clause 5.2, cover ER 7.5 in relation to Biological safety only.
7.6		Not applicable

Table ZA.1 *(continued)*

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
8.1	4.1, 4.2, 4.3, 5.2, 5.3, 5.4	Clauses 4.1 and 5.2, cover ER 8.1 in relation to Biological safety only. Clauses 4.2 and 5.3, cover ER 8.1 in relation to sterility only. Clauses 4.3 and 5.4, cover ER 8.1 in relation to Non-pyrogenenicity only.
8.2		Not applicable
8.3	6.2h	
8.4	5.3,5.4	
8.5		Not applicable
8.6		Not applicable
8.7		Not applicable
9.1	6.4	ER 9.1 is covered by clause 6.4, but only in respect of the provision of the information specified in the standard.
9.2		Not applicable
9.3		Not applicable
10		Not applicable
11		Not applicable
12		Not applicable
13.1	6.1, 6.2, 6.3,6.4	ER 13.1 is covered by standard clause 6.1, but only in respect of the labelling on the device and only in respect of: - The red and blue markings at patient connection ends; - The level markings for the air-capture chamber – if appropriate. ER 13.1 is covered by clause 6.2, but only in respect of the labelling on the unit container and only in respect of the information specified in the standard ER 13.1 is covered by clause 6.3, but only in respect of the labelling on the outer container and only in respect of the information specified in the standard
13.2	6.1c to i, 6.2,6.3,6.4	
13.3a	6.2a	Clause 6.2a, ER 13.3a in respect of the manufacturer only, and only in respect of the labelling on the unit container.
13.3b	6.2b, 6.2c, 6.2d, 6.2k	Clauses 6.2a, 6.2b, 6.2c and 6.2k cover ER 13.3b in respect of the labelling on the unit container.
13.3c	6.2e	Clause 6.2e covers ER 13.3c in respect of the labelling on the unit container only.

Table ZA.1 *(continued)*

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
13.3d	6.2, 6.3, 6.4	Clause 6.2d covers ER 13.3d in respect of the labelling on the unit container only and only if the lot number is preceded with the word "LOT" (or the harmonized symbol).
13.3e	6.2,6.3	Clause 6.2f covers ER 13.3e in respect of the labelling on the unit container only and only if the expiry date is expressed in the format year and month.
13.3f	6.2,6.3,6.4	Clause 6.2g covers ER 13.3f in respect of the labelling on the unit container only.
13.3g		Not applicable
13.3h		Not applicable
13.3i	6.3	Clause 6.3h covers ER 13.3i in respect of the labelling on the outer container only.
13.3j	6.2, 6.4	Clause 6.2 ER 13.3j but only in respect of the labelling on the unit container and only to the extent given in the standard.
13.3k	6.4	
13.3l		Not applicable
13.3m	6.2,6.3	Clause 6.2i covers ER 13.3m but only in respect of the labelling on the unit container.
13.3n		Not applicable
13.4	6.4	
13.5		Not applicable
13.6a	6.4	Clause 6.4 covers ER 13.6a in respect of all relevant clauses of 13.3 except g, h and i.
13.6b	6.4	Clause 6.4 covers ER 13.6b to the extent shown in the standard. Clause 6.4 does not cover Directive Annex 1, ER 13.6b in respect of undesirable side effects.
13.6c	6.4	Clause 6.4f covers ER 13.6c to the extent shown in the standard.
13.6d		Not applicable
13.6e		Not applicable
13.6f		Not applicable
13.6g		Not applicable
13.6h		Not Applicable
13.6i	6.2	
13.6j		Not applicable
13.6k		Not applicable
13.6l		Not applicable
13.6m	6.2 (exception i),6.4	Clause 6.2i does not cover, ER 13.6m.
13.6n		Not applicable

Table ZA.1 *(continued)*

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
13.6o		Not applicable
13.6p		Not applicable
13.6q		Not applicable

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.

To be inserted in the European Foreword of EN ISO 8637-2 at the time of its publication:

The referenced documents shown in Table ZA.2 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 ZA.2 — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	**Equivalent dated standard**	
	EN	ISO
ISO 7864	EN ISO 7864:2016	ISO 7864:2016
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-4	EN ISO 10993-4:2017	ISO 10993-4:2017
ISO 10993-7	EN ISO 10993-7:2008	ISO 10993-7:2008
ISO 10993-11	EN ISO 10993-11:2009	ISO 10993-11:2017
ISO 80369-7	EN ISO 80369-7:2017	ISO 80369-7:2016

INTERNATIONAL ISO

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2018-07-16

Extracorporeal systems for blood purification —

Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

Systèmes extracorporels pour la purification du sang —

Partie : Circuit sanguin extracorporel pour les hémodialyseurs, les hémodiafiltres et les hémofiltres

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Contents

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 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 WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

This document was prepared by Technical committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition of ISO 8637-2:2018 cancels and replaces the third edition (ISO 8638:2010), which has been technically revised. The following changes have been made:

— Figure 1, Figure 2, and Figure 3 have been revised.

A list of all the parts in the ISO 8637 series can be found on the ISO website.

Introduction

This document is concerned with the extracorporeal blood circuit manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters and haemofilters. The requirements specified in this document for the extracorporeal blood circuit will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This document therefore requires only that materials have been tested and that the methods and results are made available upon request.

The dimensions of the connectors intended for connecting the extracorporeal blood circuit to a haemodialyser, haemodiafilter or haemofilter have been revised and specified to ensure compatibility with these devices, as specified in ISO 8637-1. The design and dimensions have been selected in order to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

This document reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use.

Extracorporeal systems for blood purification —

Part 2:
Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

1 Scope

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

This document specifies requirements for the blood circuit for devices used in extracorporeal blood filtration therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration and transducer protectors (integral and non-integral) intended for use in such circuits.

This document does not apply to:

— haemodialysers, haemodiafilters or haemofilters;

— plasmafilters;

— haemoperfusion devices;

— vascular access devices;

— blood pumps;

— pressure monitors for the extracorporeal blood circuit;

— air detection devices;

— systems to prepare, maintain or monitor dialysis fluid;

— systems or equipment intended to perform haemodialysis, haemodiafiltration, haemofiltration or haemoconcentration.

NOTE 1 — Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637-1, and requirements for plasmafilters are specified in ISO 8637-3.

NOTE 2 — Extracorporeal blood tubing sets can also be used for other extracorporeal therapies such as haemoperfusion, plasmafiltration and plasma adsorption.

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 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

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 interactions 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 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*