SLOVENSKI STANDARD
SIST EN ISO 8637-2:2018

01-december-2018

Nadomešča:
SIST EN ISO 8638:2014

Zunajtelesni pretočni sistemi za čiščenje krvi - 2. del: Zunajtelesni krvni obtok za hemodializatorje, hemodiafiltre in hemofiltre (ISO 8637-2:2018)

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

Extrakorporale Systeme zur Blutreinigung - Teil 2: Extrakorporaler Blutkreislauf bei Hämodialysatoren, Hämodiafiltern und Hämofiltern (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)

Ta slovenski standard je istoveten z: **EN ISO 8637-2:2018**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 8637-2:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8637-2

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 System - Teil 2: Extrakorporaler Blutkreislauf bei Hämodialysatoren, Hämodiafiltern und Hämofiltern (ISO 8637-2:2018)

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

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 26 September 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: Rue de la Science 23, B-1040 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 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 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.

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

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
		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.
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

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this European Standard	Qualifying remarks/Notes
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
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.

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 STANDARD

ISO 8637-2

First edition
2018-07

Extracorporeal systems for blood purification —

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

Systèmes extracorporels pour la purification du sang —
Partie 2: Circuit sanguin extracorporel pour les hémodialyseurs, les hémodiafiltres et les hémofiltres

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