ILNAS

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

ILNAS-EN ISO 8637-2:2018

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

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

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

08/2018

National Foreword

This European Standard EN ISO 8637-2:2018 was adopted as Luxembourgish Standard ILNAS-EN ISO 8637-2:2018.

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- Foresee future developments
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8637-2

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Supersedes EN ISO 8638:2014

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.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 26 September 2018.

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
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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