ILNAS

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

ILNAS-EN ISO 8637-2:2024

Extracorporeal systems for blood purification - Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters,

Systèmes extracorporels pour la purification du sang - Partie 2: Circuits sanguins extracorporels et liquidiens pour les hémodialyseurs, les

Extrakorporale Systeme zur Blutreinigung - Teil 2: Extrakorporaler Blut- und Flüssigkeitskreislauf bei Hämodialysatoren, Hämodiafiltern,

04/2024

National Foreword

This European Standard EN ISO 8637-2:2024 was adopted as Luxembourgish Standard ILNAS-EN ISO 8637-2:2024.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8637-2

April 2024

ICS 11.040.20

Supersedes EN ISO 8637-2:2018

English Version

Extracorporeal systems for blood purification - Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (ISO 8637-2:2024)

Systèmes extracorporels pour la purification du sang - Partie 2: Circuits sanguins extracorporels et liquidiens pour les hémodialyseurs, les hémodiafiltres, les hémofiltres et les hémoconcentrateurs (ISO 8637-2:2024)

Extrakorporale Systeme zur Blutreinigung - Teil 2: Extrakorporaler Blut- und Flüssigkeitskreislauf bei Hämodialysatoren, Hämodiafiltern, Hämofiltern und Hämokonzentratoren (ISO 8637-2:2024)

This European Standard was approved by CEN on 15 December 2023.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye 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

Contents

Page

European foreword

This document (EN ISO 8637-2:2024) 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 October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

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 8637-2:2018.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 8637-2:2024 has been approved by CEN as EN ISO 8637-2:2024 without any modification.

International Standard

ISO 8637-2

Second edition
2024-04

Extracorporeal systems for blood purification —

Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Systèmes extracorporels pour la purification du sang —

Partie 2: Circuits sanguins extracorporels et liquidiens pour les hémodialyseurs, les hémodiafiltres, les hémofiltres et les hémoconcentrateurs

Reference number
ISO 8637-2:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page