



SLOVENSKI STANDARD SIST EN ISO 8637-2:2024

01-junij-2024

Zunajtelesni pretočni sistemi za čiščenje krvi - 2. del: Zunajtelesni krvni in tekočinski obtok za hemodializatorje, hemodiafiltre, hemofiltre in hemokoncentratorje (ISO 8637-2:2024)

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

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

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

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Ta slovenski standard je istoveten z: EN ISO 8637-2:2024

ICS:

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

EN ISO 8637-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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
hémo-filtres et les hémoconcentrateurs (ISO 8637-
2:2024)

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

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

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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.

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International Standard

ISO 8637-2

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 hémo-filtres et les
hémoconcentrateurs*

**Second edition
2024-04**

ISO 8637-2:2024(en)

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Foreword

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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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 8637-2:2018), which has been technically revised.

The main changes are:

- dimensional details of reference connectors for the testing of blood port connectors have been included together with an illustration of a conical gauge suitable to test the blood connector socket;
- blood and fluid circuits with haemodialysis equipment have been integrated throughout this document;
- the terms and definitions have been aligned with those used in other parts of the ISO 8637 series and IEC 60601-2-16;
- a risk-based approach to structural integrity testing has been introduced;
- haemocompatibility testing has been updated;
- the scope has been widened to include disposable fluid circuits.

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

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