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 hémofiltres et les hémoconcentrateurs (ISO 8637-2:2024)

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

SIST EN ISO 8637-2:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8637-2

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ICS 11.040.20

Supersedes EN ISO 8637-2:2018

English Version

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.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.

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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

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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 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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.