ICS 11.040.20, 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Júl 2024

STN	**Mimotelové systémy na čistenie krvi Časť 2: Mimotelový krvný a tekutinový obvod pre hemodialyzátory, hemodiafiltre, hemofiltre a hemokoncentrátory (ISO 8637-2: 2024)**	**STN EN ISO 8637-2** 85 6218

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/24

Obsahuje: EN ISO 8637-2:2024, ISO 8637-2:2024

Oznámením tejto normy sa ruší
STN EN ISO 8637-2 (85 6218) z januára 2019

138741

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.

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

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Ref. No. EN ISO 8637-2:2024 E

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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.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

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

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

Second edition
2024-04

Reference number
ISO 8637-2:2024(en)

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Published in Switzerland

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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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

Introduction

This document is concerned with the extracorporeal blood and fluid circuits manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters, haemofilters and heamodialysis equipment. The requirements specified in this document for the extracorporeal blood and fluid circuits will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This document therefore requires only that materials which have been tested and that the methods and results are made available upon request. There is no intention to specify, or to set limits on, the performance characteristics of the devices because such restrictions are unnecessary for the qualified user and would limit the alternatives available when choosing a device for a specific application. This document therefore requires only that materials have been tested and that the methods and results are made available upon request.

The dimensions of the connectors intended for connecting the extracorporeal blood and fluid circuits to a haemodialyser, haemodiafilter or haemofilter have been reviewed to ensure compatibility with these devices, as specified in ISO 8637-1. The design and dimensions selected are intended to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

This document reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use.

International Standard **ISO 8637-2:2024(en)**

Extracorporeal systems for blood purification —

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

1 Scope

This document specifies requirements for disposable extracorporeal blood and fluid circuits and accessories used in combination with haemodialysis equipment intended for extracorporeal blood treatment therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration.

This document does not apply to:

— haemodialysers, haemodiafilters or haemofilters;

— plasmafilters;

— haemoperfusion devices;

— vascular access devices.

NOTE 1 Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637-1.

NOTE 2 Requirements for plasmafilters are specified in ISO 8637-3.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

IEC 60601-2-16:2018, *Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*