SVENSK STANDARD
SS-EN ISO 8637-2:2018

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SWEDISH STANDARDS INSTITUTE

Extrakorporeala system för blodrening – Del 2: Extrakorporeal krets för hemodialysatorer, hemodialysfilter och dialysfilter (ISO 8637-2:2018)

Extracorporeal systems for blood purification – Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (ISO 8637-2:2018)

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Europastandarden EN ISO 8637-2:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8637-2:2018.

Denna standard ersätter SS-EN ISO 8638:2014, utgåva 1

The European Standard EN ISO 8637-2:2018 has the status of a Swedish Standard. This document contains the official version of EN ISO 8637-2:2018.

This standard supersedes the SS-EN ISO 8638:2014, edition 1

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8637-2

August 2018

ICS 11.040.40

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.

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, 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
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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.

Introduction

This document is concerned with the extracorporeal blood circuit manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters and haemofilters. The requirements specified in this document for the extracorporeal blood circuit 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 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 circuit to a haemodialyser, haemodiafilter or haemofilter have been revised and specified to ensure compatibility with these devices, as specified in ISO 8637-1. The design and dimensions have been selected in order 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.

Extracorporeal systems for blood purification —

Part 2:
Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

1 Scope

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this document.

This document specifies requirements for the blood circuit for devices used in extracorporeal blood filtration therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration and transducer protectors (integral and non-integral) intended for use in such circuits.

This document does not apply to:

— haemodialysers, haemodiafilters or haemofilters;

— plasmafilters;

— haemoperfusion devices;

— vascular access devices;

— blood pumps;

— pressure monitors for the extracorporeal blood circuit;

— air detection devices;

— systems to prepare, maintain or monitor dialysis fluid;

— systems or equipment intended to perform haemodialysis, haemodiafiltration, haemofiltration or haemoconcentration.

NOTE 1 Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637-1, and requirements for plasmafilters are specified in ISO 8637-3.

NOTE 2 Extracorporeal blood tubing sets can also be used for other extracorporeal therapies such as haemoperfusion, plasmafiltration and plasma adsorption.

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 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
air capture chamber
component intended to capture air and which can provide compliance to the blood circuit or allow pressure to be monitored

Note 1 to entry: Air capture chambers are also known as drip chambers, bubble traps or venous and arterial blood chambers.

3.2
extracorporeal blood circuit
blood tubing and integral accessory tubing, including fluid and infusion tubing, for attaching the extracorporeal blood circuit to pressure monitors and integral components

EXAMPLE (Of integral components.) Air capture chambers and transducer protectors.

3.3
fluid pathway
internal surfaces of the *extracorporeal blood circuit* (3.2)

3.4
labelling
written, printed, graphic or electronic matter that is affixed to a medical device or any of its containers or wrappers, or accompanies a medical device and which is related to identification, technical description and use of that medical device, but excluding shipping documents

3.5
pump segment
portion of the *extracorporeal blood circuit* (3.2) that is acted upon by the blood pump

3.6
transducer protector
pressure-transmitting sterile barrier
component of the *extracorporeal blood circuit* (3.2) that is intended to provide an interconnection between the extracorporeal blood circuit and the haemodialysis machine while allowing the pressure within the extracorporeal blood circuit to be measured by the machine

4 Requirements

4.1 Biological safety

Parts of the device that are intended to come into direct or indirect contact with blood shall be evaluated for freedom from biological hazards, in accordance with 5.2. Attention is drawn to the need to establish whether national regulations or national standards governing toxicology and biocompatibility testing exist in the country in which the device is produced and, if applicable, in the countries in which the device is to be marketed.

4.2 Sterility

All fluid contacting surfaces of the device, and the mating surfaces of all connectors integral to the device, shall be sterile. Conformity shall be verified in accordance with 5.3.

4.3 Non-pyrogenicity

The blood pathway of the device shall be non-pyrogenic. Conformity shall be verified in accordance with 5.4.

4.4 Mechanical characteristics

4.4.1 Structural integrity

The device shall be capable of withstanding a positive pressure of 1,5 times the manufacturer's recommended maximum pressure above atmospheric pressure and a negative pressure not exceeding 700 mmHg (93,3 kPa below atmospheric pressure) or the highest obtainable negative pressure if at high elevation, when tested in accordance with 5.5.1.

4.4.2 Connectors to haemodialyser, haemodiafilter or haemofilter

4.4.2.1 Except where the haemodialyser, haemodiafilter or haemofilter and the extracorporeal blood circuit are designed as an integral system, the dimensions of the connectors for the haemodialyser, haemodiafilter or haemofilter shall be as given in Figure 1. Conformity shall be verified in accordance with 5.5.2.

4.4.2.2 Connectors made of semi-rigid materials shall meet the performance requirements of ISO 80369-7.

4.4.3 Connectors to vascular access device

Except where the extracorporeal blood circuit and the vascular access device are an integral system, the dimensions of the connectors intended for connection to vascular access devices shall be a male 6 % (Luer) taper lock fitting (see ISO 80369-7). Connectors made of semi-rigid materials shall meet the performance requirements of ISO 80369-7. Conformity shall be verified in accordance with 5.5.3.

4.4.4 Connectors to ancillary components

All parts of the extracorporeal blood circuit intended for use with non-integral ancillary components, such as heparin lines, pressure-transducer lines, medication-administration lines and level-adjustment lines, shall terminate in fittings that meet the performance requirements of ISO 80369-7. Conformity shall be verified in accordance with 5.5.4.

4.4.5 Colour coding

The arterial patient-connection end shall be colour-coded red, and the venous patient-connection end shall be colour-coded blue. The coding shall be prominently displayed within 100 mm of the end of the tubing. Conformity to this requirement shall be verified in accordance with 5.5.5.