Nederlandse norm

NEN-ISO 8637-3

(en)

Extracorporale systemen voor bloedzuivering - Deel 3: Plasmafilters (ISO 8637-3:2018,IDT)

Extracorporeal systems for blood purification - Part 3: Plasmafilters (ISO 8637-3:2018,IDT)

Vervangt NEN-ISO 13960:2010

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- ISO 8637-3:2018,IDT

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INTERNATIONAL STANDARD

ISO 8637-3

First edition
2018-07

Extracorporeal systems for blood purification —

Part 3: Plasmafilters

Systèmes extracorporels pour la purification du sang —
Partie 3: Filtres pour plasma

Reference number
ISO 8637-3:2018(E)

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: 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*.

This first edition of ISO 8637-3:2018 cancels and replaces the second edition of ISO 13960:2010, which has been technically revised. The following changes have been made:

— the Figures relating to connector dimensions have been revised.

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

Introduction

It was not found practicable to specify materials of construction. Therefore, this document only requires that materials used have been tested, and that the testing methods and the 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.

If the plasmafilter is used with an extracorporeal circuit, the dimensions of the blood ports and filtrate ports have been specified to ensure compatibility of the device with the extracorporeal blood circuit specified in ISO 8637-2. The design and dimensions have been selected to minimize the risk of leakage of blood and the ingress of air.

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

INTERNATIONAL STANDARD **ISO 8637-3:2018(E)**

Extracorporeal systems for blood purification —

Part 3: Plasmafilters

1 Scope

This document specifies requirements and acceptance criteria (including test methods) for safety related parameters for plasmafilters. Only those requirements that are specific to plasmafilters have been included.

It specifies requirements for sterile, single-use plasmafilters, intended for use on humans.

This document does not cover matters related to toxicity. Such issues are covered in relevant parts of ISO 10993.

It does not apply to the extracorporeal circuits that can be used for plasmapheresis vascular access devices, oxygenators or active medical devices. This document does not address the replacement fluid.

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 8637-1, *Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

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 http://www.electropedia.org/

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

3.1
blood compartment
part of plasmafilter through which blood is intended to pass

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