BS ISO 8637-3:2024

BSI Standards Publication

Extracorporeal systems for blood purification

Part 3: Plasmafilters

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National foreword

This British Standard is the UK implementation of ISO 8637-3:2024. It supersedes BS ISO 8637-3:2018, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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*.

This second edition cancels and replaces the first edition (ISO 8637-3:2018), which has been technically revised.

The main changes are as follows:

— terms and definitions have been aligned with those defined in other parts of the ISO 8637 series;

— additional figures relating to a gauge to test dimensional compliance of connectors have been added;

— test methods for measurement of the sieving coefficient and haemolytic characteristics have been revised;

— requirements for accompanying documentation have been revised and extended to ensure that the risk of inadvertent use of a plasmafilter for haemofiltration is minimized.

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.

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Introduction

This document is concerned with filters intended to perform plasma filtration in humans. If such a filter is used with an extracorporeal circuit, the dimensions of the blood compartment connectors and filtrate compartment connectors 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.

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.

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Extracorporeal systems for blood purification —

Part 3: Plasmafilters

1 Scope

This document specifies requirements and test methods for plasmafilters, which are devices intended to separate plasma from blood in therapeutic plasmapheresis therapy. This document specifies the requirements for sterile, single-use plasmafilters, intended for use on humans, hereinafter collectively referred to as "the device", for use in humans. This document does not apply to;

— extracorporeal blood circuits;

— haemodialysers, haemodiafilters, haemofilters and haemoconcentrators;

— haemoperfusion devices;

— vascular access devices;

— blood pumps;

— systems or equipment intended to perform plasma separation.

NOTE 1 Requirements for the extracorporeal blood circuit are specified in ISO 8637-2.

NOTE 2 Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637-1.

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

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

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