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Extracorporeal systems for blood purification —

Part 3: Plasmafilters

Systèmes extracorporels pour la purification du sang —

Partie 3: Filtres pour plasma

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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.

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.