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Intravascular catheters — Sterile and single-use catheters —

Part 8: Catheters for extracorporeal blood treatment

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 8: Cathéters destinés au traitement extracorporel du sang

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Foreword

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This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medical products and catheters*.

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Intravascular catheters — Sterile and single-use catheters —

Part 8: Catheters for extracorporeal blood treatment

1 Scope

This document specifies general requirements for intravascular catheters, supplied in sterile condition and intended for extracorporeal blood treatments (EBT).

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 10555-1, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

ISO 10555-3, *Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters*

ISO 10555-5, *Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters*

3 Terms and definitions

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

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

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

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

3.1
catheter for extracorporeal blood treatment
catheter for EBT
tubular device, single or multi-lumen, designed to be inserted into the vascular system for blood purification purposes, such as hemodialysis, hemofiltration, apheresis, and therapeutic plasma exchange

3.2
priming volume
total amount of space available to be filled with solution

3.3
arterial flow direction
blood flow direction from the patient to the extracorporeal blood circuit

3.4
venous flow direction
blood flow direction from the extracorporeal blood circuit to the patient

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