INTERNATIONAL STANDARD

ISO 10555-6

First edition
2015-04-15

AMENDMENT 1
2019-09

Intravascular catheters — Sterile and single-use catheters —

Part 6: Subcutaneous implanted ports

AMENDMENT 1

Cathéters intravasculaires — Cathéters stériles et non réutilisables —
Partie 6: Chambres à cathéter implantables

AMENDEMENT 1

Reference number
ISO 10555-6:2015/Amd.1:2019(E)

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

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4.6

Replace the text with the following:

For devices for which flow rate is defined, when tested in accordance with

— ISO 10555-1:2013, Annex E, for all ports, and

— ISO 10555-1:2013, Annex G, for ports indicated for power injection,

the flow rate for each lumen shall be a minimum of 80 % of that stated in the instructions for use for catheters of nominal outside diameter less than 1,0 mm or a minimum of 90 % of that stated in the instructions for use for catheters of nominal outside diameter equal to 1,0 mm or greater.

If the flowrate through hydratable catheters is determined, it shall be determined in post-hydration states.

ICS 11.040.25
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