# 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** 

iTeh STANDARD PRE L'EUR Cathéters et non réutilisables — Cathéters stériles et non réutilisables — (S Partie 6: Chambres à cathéter implantables

AMENDEMENT 1 ISO 10555-6:2015/Amd 1:2019 https://standards.iteh.ai/catalog/standards/sist/8c9db97b-ebcd-4314-a9fl-4ffc7b430eb2/iso-10555-6-2015-amd-1-2019



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

ISO 10555-6:2015/Amd 1:2019

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## Intravascular catheters — Sterile and single-use catheters —

### Part 6:

### Subcutaneous implanted ports

### **AMENDMENT 1**

4.6

Replace the text with the following:

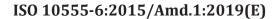
For devices for which flow rate is defined, when tested in accordance with

- 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.

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