SIST

SLOVENSKI STANDARD
SIST EN ISO 10555-6:2017/oprA1:2019

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Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 6. del: Podkožni vsadki - Dopolnilo A1 (ISO 10555-6:2015/DAM 1:2019)

Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports - Amendment 1 (ISO 10555-6:2015/DAM 1:2019)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung — Teil 6: Subkutan implantierte Ports - ÄNDERUNG 1 (ISO 10555-6:2015/DAM 1:2019)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 6: Chambres à cathéter implantables - Amendement 1 (ISO 10555-6:2015/DAM 1:2019)

Ta slovenski standard je istoveten z: EN ISO 10555-6:2017/prA1

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

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DRAFT AMENDMENT
ISO 10555-6:2015/DAM 1

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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

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

This amendment is intended to correct an error in subclause 4.6 for flow rate, where a reference to ISO 10555-1:2013, Annex G is inserted.

A list of all parts in the ISO 10555- series can be found on the ISO website.

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Intravascular catheters — Sterile and single-use catheters —

Part 6: Subcutaneous implanted ports

AMENDMENT 1

4.6 Flow rate

Add the following in the second line:

For devices for which flow rate is defined, when tested in accordance with ISO 10555-1:2013, Annex E, for ports not indicated for power injection or Annex C for ports indicated for power injection, the flow rate for each lumen shall be a minimum of 80 % of that stated by the manufacturer for catheters of nominal outside diameter less than 1,0 mm or a minimum of 90 % of that stated by the manufacturer 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.