INTERNATIONAL STANDARD

ISO 10555-1

Second edition
2013-06-15

AMENDMENT 1
2017-11

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

AMENDMENT 1

Cathéters intravasculaires — Cathéters stériles et non réutilisables — Partie 1: Exigences générales

AMENDEMENT 1

Reference number
ISO 10555-1:2013/Amd.1:2017(E)

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

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

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4.6

Add the following Note after Table 1:

NOTE The forces experienced during clinical use may be greater than the values listed in Table 1, e.g. the expected forces applied to a delivery system during clinical use to access the intended location, to deploy the device, or to withdraw the system. If the forces experienced during clinical use are determined by the manufacturer to be greater than the values listed in Table 1, the acceptance criteria for the peak tensile force of each test piece is to be as determined by the manufacturer based on risk assessment.

Annex B

Replace B.3.2 with the following:

Place the test pieces to be conditioned (see B.3.1) in appropriate aqueous medium at (37 ± 2) °C for a clinically appropriate period of time or a minimum of 2 h. Test in accordance with B.3.3 to B.3.8 immediately after conditioning.

ICS 11.040.25
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