INTERNATIONAL STANDARD

ISO 10555-1

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Amendment 1
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Sterile, single-use intravascular catheters —

Part 1:
General requirements

AMENDMENT 1

Cathéters intravasculaires stériles, non réutilisables —

Partie 1: Prescriptions générales

AMENDEMENT 1

Reference number
ISO 10555-1:1995/Amd.1:1999(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Amendment 1 to International Standard ISO 10555-1 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

The purpose of this amendment is to add to ISO 10555-1 general requirements for hydratable catheters.

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Page 1

Clause 3 Definitions

Delete existing definitions for 3.5 and 3.6, and substitute the following definitions:

3.5 effective length, *l*: Length of the catheter, or pre- and post-hydration lengths of hydratable catheters, that can be inserted into the body (see figure 1).

3.6 outside diameter: Maximum diameter of the catheter, or pre- and post-hydration maximum diameters of hydratable catheters, that can be inserted into the vessel.

Add the following new definitions:

3.8 hydratable intravascular catheter: Intravascular catheter consisting of a material that manifests clinically significant hydration when subjected to an aqueous medium.

3.9 post-hydration: State of a hydratable intravascular catheter after immersion in water at (37 ± 2) °C for 2 h.

3.10 clinically significant hydration: Hydrated state in which either the post-hydration effective length is greater than the pre-hydration effective length by more than 4 mm or 1 % of the effective length, whichever is the lesser, or the post-hydration outside diameter is greater than the pre-hydration outside diameter by 10 % or more.

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Clause 4 Requirements

In the note in **table 1**, add the following text at the end of the sentence:

(pre-hydration outside diameter for hydratable intravascular catheters).

4.6.1 Add the following paragraph:

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

4.6.2 Add the following paragraph:

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

Add the following new subclause.

4.8 Flowrate

This part of ISO 10555 does not specify requirements for flowrate, but if the flowrate through hydratable catheters is determined, it shall be determined in both the pre- and post-hydration states.

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Clause 6 Information to be supplied by the manufacturer

Add the following text to items b) and c):

…, including pre- and post-hydration values for hydratable intravascular catheters.

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Clause B.1 Principle

Add the following new sentence at the end of B.1:

Hydratable catheters are tested in both the pre- and post-hydration states.

Subclause B.3.1 Add the following new paragraph:

For hydratable catheters, prepare identical test pieces from two catheters. Condition one test piece in accordance with B.3.2. Do not condition the other test piece; test it immediately in accordance with B.3.3 to B.3.8.

Subclause B.3.2 Delete the existing text and replace by the following:

Place the test pieces to be conditioned (see B.3.1) in distilled or deionized water at a temperature of (37 ± 2) °C for 2 h. Test in accordance with B.3.3 to B.3.8 immediately after conditioning.

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Clause C.4 Procedure

Add the following new subclause:

C.4.5 For hydratable intravascular catheters, carry out the steps in C.4.1 to C.4.4 on catheters in both the pre- and post-hydration states.

Clause C.5 Test report

Add the following text to item b):

(in both the pre- and post-hydration states for hydratable intravascular catheters).

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Clause D.4 Procedure

Add the following new subclause:

D.4.6 For hydratable intravascular catheters, carry out the steps in D.4.1 to D.4.5 on catheters in both the pre- and post-hydration states.