

# INTERNATIONAL STANDARD

# ISO 10555-1

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**Amendment 1**  
1999-07-15

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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

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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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International Organization for Standardization  
Case postale 56 • CH-1211 Genève 20 • Switzerland  
Internet iso@iso.ch

Printed in Switzerland

# Sterile, single-use intravascular catheters —

## Part 1: General requirements

### AMENDMENT 1

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#### 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  $(37 \pm 2)$  °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  $(37 \pm 2) ^\circ\text{C}$  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.