SLOVENSKI STANDARD
SIST EN ISO 10555-1:2000/A1:2000

01-julij-2000

Sterilni žilni katetri za enkratno uporabo - 1. del: Splošne zahteve (ISO 10555-1:1996/AM1:1999)

Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1996/AM1:1999)

Sterile intravaskuläre Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO 10555-1:1996/AM1:1999)

Cathéters intravasculaires stériles, non réutilisables - Partie 1: Prescriptions générales (ISO 10555-1:1996/AM1:1999)

Ta slovenski standard je istoveten z: **EN ISO 10555-1:1996/A1:1999**

ICS:

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

SIST EN ISO 10555-1:2000/A1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1:1996/A1

July 1999

ICS 11.040.20

English version

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This amendment A1 modifies the European Standard EN ISO 10555-1:1996; it was approved by CEN on 25 June 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of this Amendment EN ISO 10555-1:1996/A1:1999 to the EN ISO 10555-1:1996 from Technical Committee ISO/TC 84 “Medical devices for injections” of the International Organization for Standardization (ISO) has been taken over as an Amendment to the European Standard by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 10555-1:1996 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2000, and conflicting national standards shall be withdrawn at the latest by January 2000.

This Amendment to the European Standard EN ISO 10555-1:1996 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the Amendment to the International Standard ISO 10555-1:1996/Amendment 1:1999 has been approved by CEN as an Amendment to the European Standard without any modification.

INTERNATIONAL STANDARD

ISO 10555-1

First edition
1995-06-15

Amendment 1
1999-07-15

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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Sterile, single-use intravascular catheters —

Part 1:
General requirements

AMENDMENT 1

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.

Page 3

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.

Page 4

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.

Page 6

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.

Page 7

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).

Page 8

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.