SLOVENSKI STANDARD
SIST EN ISO 10555-5:2000/A1:2000

01-november-2000

Sterilni žilni katetri za enkratno uporabo - 5. del: Periferni katetri z notranjo iglo (ISO 10555-5:1996/AM:1999)

Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:1996/AM:1999)

Sterile intravaskuläre Katheter zur einmaligen Verwendung - Teil 5: Periphere Katheter mit innen liegender Kanüle (ISO 10555-5:1996/FDAM:1999)

Cathéters intravasculaires stériles, non réutilisables - Partie 5: Cathéters périphériques a aiguille interne (ISO 10555-5:1996/FDAM:1999)

Ta slovenski standard je istoveten z: **EN ISO 10555-5:1997/A1:2000**

ICS:

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

SIST EN ISO 10555-5:2000/A1:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10555-5:1997/A1

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English version

Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:1996/AM:1999)

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This amendment A1 modifies the European Standard EN ISO 10555-5:1997; it was approved by CEN on 9 June 2000.

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

Ref. No. EN ISO 10555-5:1997/A1:2000 E

Foreword

The text of this Amendment EN ISO 10555-5:1997/A1:2000 to the EN ISO 10555-5:1997 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 10555-5:1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2001, and conflicting national standards shall be withdrawn at the latest by January 2001.

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 10555-5:1996/Amendment 1:1999 has been approved by CEN as an Amendment to the European Standard without any modification.

INTERNATIONAL STANDARD

ISO 10555-5

First edition
1996-06-15

AMENDMENT 1
1999-01-15

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1999-07-15

Sterile, single-use intravascular catheters —

Part 5:
Over-needle peripheral catheters

AMENDMENT 1

Cathéters intravasculaires stériles, non réutilisables —

Partie 5: Cathéters périphériques à aiguille interne

AMENDEMENT 1

Reference Number
ISO 10555-5:1996/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 10555-5:1996 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 introduce into ISO 10555-5:1996 requirements for the leak-tightness of vent fittings.

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Sterile, single-use intravascular catheters —

Part 5:
Over-needle peripheral catheters

AMENDMENT 1

Page 1, clause 1, Scope

Add the following to the end of the note:

"and to ISO 14972 which specifies requirements for sterile obturators for use with over-needle peripheral catheters".

Page 3, subclause 4.4.4, Vent fitting

Delete the text and substitute the following:

"A vent fitting shall be provided. When tested in accordance with annex E, fluid shall not leak out of the vent fitting within 15 s."

Page 10, annex E, Bibliography

Change annex E to annex F.

Add the following reference:

"[2] ISO 14972:1998, *Sterile obturators for single use with over-needle peripheral intravascular catheters.*"

Page 10

Add the following new annex as annex E.

Annex E
(normative)

Determination of liquid leakage from vent fitting

E.1 Principle

The catheter is connected to a source of simulated blood under hydrostatic pressure. The fluid is allowed to flow into the needle, and the time taken for fluid to leak through the vent fitting is measured.

E.2 Test fluid

E.2.1 Prepare a solution of sodium chloride [0,9 % (*M/V*)] by dissolving 9 g of reagent grade sodium chloride in distilled or deionized water to make 1 litre of solution.

E.2.2 Prepare the test fluid by mixing 550 ml of sodium chloride solution (E.2.1) and 450 ml of glycerol of USP grade or better.

NOTE To improve the visibility of the solution, a colorant such as red or blue food dye may be incorporated.

E.3 Apparatus

E.3.1 **Constant-level tank**, to provide a hydrostatic head of (400 ± 20) mm, fitted with a delivery tube of inside diameter not less than 3 mm having a clamp or valve and at its end a puncturable membrane (e.g. a latex cap). See figure E.1 for an example of such apparatus.

E.3.2 **Stopwatch**, or similar device.

E.4 Procedure

E.4.1 Supply the constant-level tank (E.3.1) with test fluid (E.2) at (23 ± 2) °C.

E.4.2 Remove all air from the delivery tube and close the clamp or valve.

E.4.3 Insert the tip of the needle tube through the membrane, ensuring that the needle tube is kept horizontal at ± 5 degrees.

E.4.4 Open the clamp or valve so as to allow fluid to enter the needle tube. Measure the time taken for fluid to form the first falling drop at the back of the vent fitting.

E.5 Test report

The test report shall contain at least the following information:

a) the identity of the catheter being tested;

b) the time, in seconds, for the first drop of test fluid to fall.