SLOVENSKI STANDARD
SIST EN 1618:2000

01-januar-2000

Katetri, razen žilnih (intravaskularnih) katetrov - Preskusne metode za ugotavljanje splošnih lastnosti

Catheters other than intravascular catheters - Test methods for common properties

Nicht-intravasale Katheter - Prüfverfahren für allgemeine Eigenschaften

Cathéters autres que les cathéters intravasculaires - Méthodes d'essai des propriétés communes

Ta slovenski standard je istoveten z: **EN 1618:1997**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN 1618:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1618

February 1997

ICS 11.040.20

Descriptors: medical equipment, catheters, tests, characteristics, corrosion resistance, mechanical strength, leaktightness, flow rate

English version

Catheters other than intravascular catheters - Test methods for common properties

Cathéters autres que les cathéters intravasculaires - Méthodes d'essai des propriétés communes

Nicht-intravasale Katheter - Prüfverfahren für allgemeine Eigenschaften

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by BSI.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade association, and supports essential requirements of the EU Directive(s).

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

Annexes A, B, C, D, E and F form normative parts of this standard. Annex ZA is for information only.

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

1 Scope

This European Standard specifies test methods for common properties for catheters as they relate to the device ready for clinical use. The purpose of the standard is to ensure uniformity in the evaluation of catheter properties.

This European Standard is not applicable to intravascular catheters.

2 Test methods and results

The test methods are given in annexes A to F and results shall be expressed as e.g.:

"Corrosion test according to EN 1618: No sign of corrosion".

Unless otherwise specified, tolerances on all variables in the test methods shall be ± 10 %.

Annex A (normative)

Test method for corrosion resistance of metallic components

A.1 Principle

The catheter is immersed in the sodium chloride solution, then in boiling distilled water, and afterwards the metallic components are examined visually for evidence of corrosion.

A.2 Reagents

A.2.1 ***Saline solution***, comprising 0,9 % m/v of analytical reagent grade sodium chloride in freshly prepared, distilled water.

A.2.2 ***Distilled or deionized water.***

A.3 Apparatus

Borosilicate glass beakers.

A.4 Procedure

Immerse the catheter in the saline solution (A.2.1) in a glass beaker (A.3) at (23 ± 2) °C for 5 h. Remove the test specimen and immerse it in boiling distilled water (A.2.2) for 30 min. Allow the water and the test specimen to cool to, and remain at, (23 ± 2) °C for 48 h. Remove the test specimen and allow it to dry at (23 ± 2) °C. Disassemble specimens that have two or more components which are intended to be separable in use. Do not strip away or cut open any opaque coatings on metallic components. Inspect the metallic components of the specimen visually for signs of corrosion.

A.5 Test report

The test report shall include the following information:

a) identity of catheter;

b) statement as to whether corrosion occurred during the test.

Annex B (normative)

Test method for tensile properties

B.1 Principle

Test pieces of a catheter are chosen so that each tubular portion, each junction between hub or connector and tubing and each junction between tubular portions is tested. A tensile force is applied to each test piece until the tubing breaks or the junction separates or until a specified force is applied.

B.2 Apparatus

Tensile testing apparatus, capable of exerting a force of greater than 15 N.

B.3 Procedure

B.3.1 Condition those parts of the catheter that are intended for insertion into the body in an atmosphere of 100 % relative humidity (RH) or water and a temperature of (37 ± 2) °C for 2 h. Condition the remainder of the catheter at 40 % RH to 60 % RH and a temperature of (23 ± 2) °C. Test immediately after conditioning.

B.3.2 Select a test piece from the catheter to be tested. Include in the test piece the hub or connector, if present, and the junction between segments, e.g. between the tubing and the tip, if present. Exclude distal tips of lengths less than 3 mm from the test piece.

B.3.3 Fix the test piece in the tensile testing apparatus. If a hub or connector is present, use an appropriate fixture to avoid deforming the hub or connector.

B.3.4 Measure the gauge length of the test piece (i.e. the distance between the jaws of the tensile testing apparatus or the distance between the hub or connector and the jaw holding the other end of the test piece, as appropriate).

B.3.5 Apply a tensile strain at a unit strain rate of 20 mm/min/per millimetre of gauge length (see table B.1) until the test piece separates into two or more pieces, or until a specified force is applied.

Note the value of the applied tensile force, in Newtons.

B.3.6 If testing a catheter that consists of a single tubular portion having regions of different outside diameter, repeat B.3.2 to B.3.5 on test pieces of each different diameter.

B.3.7 If testing a catheter that has a side port or side ports:

a) repeat B.3.2 to B.3.5 on each side port;

b) repeat B.3.2 to B.3.5 on a test piece that includes the joint between a side port and the adjacent part of that portion of the catheter intended to be introduced into the body;

c) repeat B.3.7 b) for each joint.

B.3.8 Do not perform more than one test on each test piece.

Table B.1: Example of conditions for a 20 mm/min strain rate per millimetre of gauge length

Gauge length (mm)	Testing speed (mm/min)
10	200
20	400
25	500

B.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) the force at break, or the specified force applied, and outside diameter of each test piece.