SLOVENSKI STANDARD
SIST EN 1617:2000

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Sterilni drenažni katetri in dodatki za enkratno uporabo

Sterile drainage catheters and accessory devices for single use

Sterile Drainagekatheter und Zubehör zur einmaligen Verwendung

Sondes et dispositifs accessoires stériles de drainage, non réutilisables

Ta slovenski standard je istoveten z: **EN 1617:1997**

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English version

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Sterile Drainagekatheter und Zubehör zur einmaligen Verwendung

This European Standard was approved by CEN on 1997-01-10. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a 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.

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CEN

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

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

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 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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

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.

Annexes A and B form normative parts of this standard.

Annex C is given for information only.

1 Scope

This European Standard specifies requirements for sterile, single use drainage catheters, wound drainage systems and components thereof designed for drainage of fluids to the exterior by means of gravity or negative pressure.

This European Standard does not apply to:

a) catheters of less than 2 mm outside diameter;

b) suction catheters for use in the respiratory tract (see prEN 1733);

c) tracheal catheters (tracheal tubes) (see prEN 1782).

NOTE: Urinary tract catheters are covered in EN 1616.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publications referred to applies.

EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled 'Sterile'
EN 980	Information supplied by the manufacturer for medical devices - Graphical symbols for medical devices
prEN 1041	Terminology, Symbols and Information provided with Medical Devices - Information supplied by the manufacturer with medical devices
EN 1618 : 1997	Catheters other than intravascular catheters - Test methods for common properties

3 Definitions

For the purposes of this European Standard, the following definitions apply.

3.1 drainage catheter: Tube designed for short or long term percutaneous or surgical insertion into a fluid collection or surgical wound.

3.2 collection device: Bag, bellows, bottle or other container constituting a part of a drainage system designed for collecting liquids and connected to the drainage catheter directly or via a connecting tube.

3.3 drainage system: Drainage catheter and collection device(s) and, where applicable, other accessories such as suction source(s), connecting tube(s), connector(s) or trocar(s).

NOTE: A drainage system may be supplied either in the ready-for-use state or in a state requiring the assembly of some components by the user. Drainage may be achieved either by gravity, by negative pressure generated by an external power source, by manipulation by the user, or by the pre-evacuation of the collection device.

3.4 connecting tube: Tube designed for the assembly of components of a drainage system.

3.5 trocar: Needle, pointed rod, sleeve or any combination thereof which assists in inserting the drainage catheter into the body tissue or cavity.

3.6 suction source: Self-contained device capable of exerting a negative pressure on a drainage catheter or system.

NOTE: The suction source may be the collection device.

4 Requirements

4.1 Kink stability

NOTE: This sub-clause will be prepared when a test method has been developed.

4.2 Resistance to deformation

The drainage system or any component thereof intended to operate under negative pressure shall not show deformation sufficient to impair the function of the device at the maximum negative pressure stated by the manufacturer.

This shall be determined on the sterilized, ready-for-use product as described in annex A.

4.3 Force at break

4.3.1 *Connections*

When tested according to annex F of EN 1618 : 1997 the minimum force at break for connections shall be as given in table 1.

Table 1: Minimum force at break of connections

Nominal outside diameter (mm)	Minimum force at break (N)
2 to 4	5
>4	15

4.3.2 *Drainage catheters and all other parts of the system*

When tested according to annex B of EN 1618 : 1997 the minimum force at break shall be as given in table 2.

Table 2: Minimum force at break of catheters and other parts of the system

Nominal outside diameter (mm)	Minimum force at break (N)
2 to 4	10
>4	20

4.4 Radio-detectability

NOTE: This clause will be prepared when a test method has been developed.

4.5 Freedom from leakage

When tested according to annex D of EN 1618 : 1997 neither the drainage system nor any components thereof shall leak at the maximum negative pressure stated by the manufacturer.

4.6 Impact resistance

The collection device shall not leak when tested in accordance with annex B.

The suction source shall not show any loss of vacuum greater than 2 % when tested in accordance with annex B.

4.7 Biocompatibility

The drainage catheter and any other component of the drainage system intended to channel fluid into the patient shall be evaluated for biocompatibility and shall be free from biological hazard.

NOTE: Methods for evaluation for biocompatibility are given in EN 30993.

4.8 Sterility

The device shall comply with EN 556.

4.9 Corrosion test

When tested in accordance with the method given in annex A of EN 1618 : 1997, the test specimen shall not show any evidence of corrosion.

5 Labelling

In addition to the requirements of EN 980 and prEN 1041 the following product-specific details shall be presented on the individual packaging:

a) size of the drainage catheter (i.e. outside diameter expressed in millimetres and length expressed in millimetres or centimetres);

b) radio-detectability if claimed;

c) effective collection capacity of the collection device expressed in millilitres;

d) the vacuum stability of any pre-evacuated suction source, given as the date when at least 80 % of the initial negative pressure as stated on the label will remain.

NOTE: This may be the "use until date" as defined in prEN 1041.

e) the maximum negative pressure in Pascals (Pa) which the drainage system, or any component thereof supplied separately, can withstand.

NOTE: If the suction source is supplied with the system, this figure is the maximum operating pressure of the suction source.