



SLOVENSKI STANDARD
SIST EN 12439:2000
01-januar-2000

Sterilni rektalni katetri za enkratno uporabo

Sterile rectal catheters for single use

Sterile Rektalkatheter zur einmaligen Verwendung

Sondes rectales stériles non réutilisables

Ta slovenski standard je istoveten z: EN 12439:1998

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ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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EUROPEAN STANDARD

EN 12439

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 1998

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Descriptors: medical equipment, rectal catheters, disposable equipment, definitions, specifications, dimensions, designation, tensile strength, gas permeability, labelling, packing, storage

English version

Sterile rectal catheters for single use

Sondes rectales stériles non réutilisables

Sterile Rektalkatheter zur einmaligen Verwendung

This European Standard was approved by CEN on 2 October 1998.

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.

This European Standard 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.

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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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

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.

The document is based on DIN 13273-4 '*Catheters for medical use - Part 4: Single-use rectal catheters*'.

Annex A is given for information only.

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1 Scope

This European Standard specifies requirements for single-use rectal catheters intended to be inserted into the rectum of a patient, for emptying, rinsing or filling purposes.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. The 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 publication referred to applies.

EN 556:1994+A1:1998 *Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "Sterile"*

EN 1041 *Information supplied by the manufacturer with medical devices*

EN 1618 *Catheters other than intravascular catheters - Test methods for common properties*

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3 Definitions

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

3.1 rectal catheter: Medical device consisting of a catheter tube, which can be fitted with a connector with tapered bore, intended to be inserted into the rectum of a patient.

3.2 collapse: Flattening of the shaft, obstructing the flow through the catheter.

4 Requirements

4.1 General

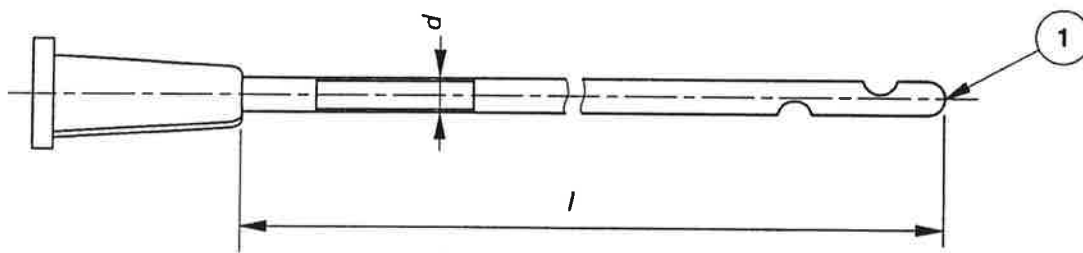
The tests to ascertain that requirements are fulfilled shall be performed on the product in the ready-for-use state.

4.2 Dimensions and designation

Rectal catheter dimensions should be defined as designated in figure 1.

The area of any eye shall not exceed the cross-sectional area of the lumen, and the tip shall be rounded and closed.

NOTE: The design of the catheter in figure 1 is an example and is given for information only. The size and position of the catheter eyes should not compromise the stiffness required for catheter insertion.



l = effective length
 d = outer diameter

1 Closed, rounded tip

Figure 1: Designation of dimensions

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4.3 Biocompatibility

The catheter shall be evaluated for biocompatibility, and shall be free from biological hazard.

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

4.4 Kink stability

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

4.5 Surface

When the catheter is ready for use (i.e. treated according to the manufacturer's instructions) and is examined by normal or corrected-to-normal vision, the surface of the shaft, tip, and eyes shall appear free from extraneous matter.

The shaft and any openings in the tip shall be designed so as to minimize the risk of serious injury to mucous membranes

4.6 Tensile properties

When tested as described in annex B of EN 1618, the catheter shall not break and the catheter and connector shall not become separated at an applied force of 15N or less.

4.7 Collapse

4.7.1 When tested as described in 4.7.2, the catheter shall not collapse.

4.7.2 Place the catheter with eyes blocked in a water bath at a temperature of $(37 \pm 2)^{\circ}\text{C}$ and keep it in the bath until temperature equilibrium has been reached. Apply a pressure of -10kPa to the catheter for a period of 15s. Examine the catheter for signs of collapse.

4.8 Air leakage

When tested as described in annex C of EN 1618 at a test pressure of 10 kPa, the joint between the catheter and the connector shall not leak.

4.9 Sterility

The catheter shall comply with EN 556:1994+A1:1998.

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5 Labelling

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

- a) Outer diameter, in millimetres, as designated in figure 1;
- b) Effective length, in millimetres, as designated in figure 1;
- c) If the product contains latex, it shall be labelled to that effect.

NOTE: Other units of measurement can be used in addition to the SI units specified in 5a) and 5b).