EESTI STANDARD EVS-EN 12439:1999

Ühekordseks kasutamiseks ettenähtud steriilsed rektaalkateetrid (pärasoolekateetrid)

Sterile rectal catheters for single use

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12439:1999 sisaldab Euroopa standardi EN 12439:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12439:1999 consists of the English text of the European standard EN 12439:1998. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev standard esitab nõuded ühekordselt kasutatavatele rektaalkateetritele (pärasoolekateetritele), mida patsiendile pärasoole kaudu sisseviiduna kasutatakse tühjendamiseks, loputamiseks või täitmiseks.	**Scope:**

ICS 11.040.20

Võtmesõnad: gaasiläbilaskvus, ladu, meditsiiniaparatuur, mõõtmed, määratlused, pakkimine, pärast kasutamist hävitatavad vahendid, rektaalkateetrid (pärasoolekateetrid), sildiga märgistamine, tehnilised andmed, tõmbetugevus, tähistus

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Descriptors: Rectal catheters.

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 1998-10-02.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

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

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

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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.

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*

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.