SLOVENSKI STANDARD
SIST EN 1616:2000/A1:2000

01-januar-2000

Sterilni uretralni katetri za enkratno uporabo

Sterile urethral catheters for single use

Sterile Harnblasenkatheter zur einmaligen Verwendung

Sondes urinaires stériles non réutilisables

Ta slovenski standard je istoveten z: **EN 1616:1997/A1:1999**

ICS:

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

SIST EN 1616:2000/A1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1616:1997/A1

March 1999

ICS 11.040.20

Descriptors: medical equipment, disposable equipment, urinary tract catheters, specifications, dimensions, flow rates, tensile strength, junctions, safety, labelling

English version

Sterile urethral catheters for single use

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Sterile Hamblasenkatheter zur einmaligen Verwendung

This amendment A1 modifies the European Standard EN 1616:1997; it was approved by CEN on 13 February 1999.

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 1616:1997/A1:1999 E

FOREWORD

This Amendment EN 1616:1997/A1:1999 to EN 1616:1997 has been prepared 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 1616:1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1999, and conflicting national standards shall be withdrawn at the latest by September 1999.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.

NOTE: The purpose of this amendment is to correct the inadvertent omission of potassium dihydrogen orthophosphate from A.2.1.

Revised text

A.2.1. Delete the list of components of simulated urine, and substitute the following:

Urea	25,0 g
Sodium chloride	9,0 g
Disodium hydrogen orthophosphate, anhydrous	2,5 g
Potassium dihydrogen orthophosphate	2,5 g
Ammonium chloride	3,0 g
Creatinine	2,0 g
Sodium sulphite, hydrated	3,0 g
Distilled water	to 1,0 l