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Edition 1, EN amdt 1 and nat. amdt 1

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Edition 1 and EN amdt 1

Any reference to SABS EN 1616 is deemed
to be a reference to this standard
(Government Notice No. 1373 of 8 November 2002)

SOUTH AFRICAN NATIONAL STANDARD

Sterile urethral catheters for single use

This national standard is the identical implementation of EN 1616:1997 and EN amendment 1, and is adopted with the permission of CEN, rue de Stassart 36, B-1050 Brussels.

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Table of changes

Change No.	Date	Scope
EN amdt 1	1999	Amended to include potassium dihydrogen orthophosphate in the list of components of simulated urine (A.2.1).
Nat. amdt 1	2009	Amended to change the designation from SABS to SANS, with no technical changes.

National foreword

This South African standard was approved by National Committee SABS/TC 1039, *Medical devices*, in accordance with procedures of the SABS Standards Division, in compliance with annex 3 of the WTO/TBT agreement.

This SANS document was published in October 2009.

This SANS document supersedes SABS EN 1616:1997 (first edition).

Reaffirmed and reprinted in February 2014.
This document will be reviewed every five years
and be reaffirmed, amended, revised or withdrawn.

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

Sondes urinaires stériles non réutilisables

Sterile Harnblasenkatheter 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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