SVENSK STANDARD
SS-EN ISO 20696:2018

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Sterila urinkatetrar för engångsbruk (ISO 20696:2018)

Sterile urethral catheters for single use (ISO 20696:2018)

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Europastandarden EN ISO 20696:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 20696:2018.

Denna standard ersätter SS-EN 1616, utgåva 1

The European Standard EN ISO 20696:2018 has the status of a Swedish Standard. This document contains the official version of EN ISO 20696:2018.

This standard supersedes the SS-EN 1616, edition 1

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20696

July 2018

ICS 11.040.25

Supersedes EN 1616:1997

English Version

Sterile urethral catheters for single use (ISO 20696:2018)

Sondes urinaires stériles non réutilisables (ISO 20696:2018)

Sterile Harnblasenkatheter zur einmaligen Verwendung (ISO 20696:2018)

This European Standard was approved by CEN on 5 May 2018.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 20696:2018: E

Contents

Page

European foreword

This document (EN ISO 20696:2018) has been prepared by Technical Committee ISO/TC 84 " Devices for administration of medicinal products and catheters " in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1616:1997.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 20696:2018 has been approved by CEN as EN ISO 20696:2018 without any modification.

Introduction

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Sterile urethral catheters for single use

1 Scope

This document specifies requirements and test methods for sterile urethral catheters for single use, with or without a balloon.

This document does not include drainage catheters covered by ISO 20697, e.g. ureteral catheters, nephrostomy catheters, and suprapubic catheters. This document also excludes ureteral stents.

NOTE Ureteral stents are covered in ASTM F1828-97.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:—[1)], *Medical devices — Application of risk management to medical devices*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 80369-1, *Small bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
balloon capacity
volume of liquid to be introduced into the catheter in order to fill the inflation channel and inflate the balloon

3.2
coating
substance applied to the surface of the catheter

3.3
compliant balloon
balloon that continues to expand in size as internal pressure increases

3.4
effective length
L_1
length of the catheter that can be inserted into the body

1) To be published (revises ISO 14971:2007). Stage at time of publication ISO/DIS 14971:2018.