

SVENSK STANDARD

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Sterila urinkatetrar för engångsbruk (ISO 20696:2018)

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

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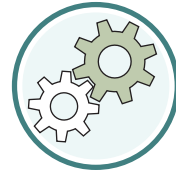
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Denna standard ersätter SS-EN 1616, utgåva 1

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

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EUROPEAN STANDARD

EN ISO 20696

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

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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.