

ÜHEKORDSELT KASUTATAVAD STERIILSED
URETRAALKATEETRID (KUSITIKATEETRID)

Sterile urethral catheters for single use (ISO
20696:2018, Corrected version 2019-12)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 20696:2018 sisaldab Euroopa standardi EN ISO 20696:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 20696:2018 consists of the English text of the European standard EN ISO 20696:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 04.07.2018.	Date of Availability of the European standard is 04.07.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.25

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

**Sterile urethral catheters for single use (ISO 20696:2018,
Corrected version 2019-12)**

Sondes urinaires stériles non réutilisables (ISO
20696:2018, Version corrigée 2019-12)

Sterile Harnblasenkatheter zur einmaligen
Verwendung (ISO 20696:2018, korrigierte Fassung
2019-12)

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

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 11 December 2019.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, 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: Rue de la Science 23, B-1040 Brussels

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, Corrected version 2019-12 has been approved by CEN as EN ISO 20696:2018 without any modification.

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Intended performance	3
5 General requirements	3
5.1 Risk management	3
5.2 Biocompatibility	3
5.3 Detectability	3
5.4 Surface finish	3
5.5 Size designation	3
5.5.1 General	3
5.5.2 Outer diameter	3
5.5.3 Effective shaft lengths	4
5.6 MRI compatibility	5
5.7 Connector	5
5.8 Sterilization	5
6 Specific requirements	5
6.1 Strength	5
6.2 Connector security	5
6.3 Balloon safety	5
6.4 Catheter inflation lumen integrity and volume maintenance	5
6.4.1 General	5
6.4.2 Compliant balloon	6
6.4.3 Non-compliant balloon	6
6.5 Flow rate	6
6.6 Corrosion resistance	7
6.7 Kink stability	7
6.8 Peak tensile force	7
6.9 Inflated balloon resistance to traction	7
7 Information to be supplied by the manufacturer	8
7.1 General	8
7.2 Marking on the device and/or packaging	8
7.3 Instructions for use	8
Annex A (normative) Test method for determining the strength of the catheter	10
Annex B (normative) Test method for determining the security of fit of the drainage funnel	14
Annex C (normative) Test method for determining balloon safety	16
Annex D (normative) Test method for determining inflation lumen leakage and/or function and/or balloon deflation (catheter with compliant balloon)	18
Annex E (normative) Test method for determination of flow rate through catheter	20
Annex F (normative) Test method for corrosion resistance	22
Annex G (informative) Test method for determining kink stability	23
Annex H (normative) Test method for determining peak tensile force of urethral catheter	25
Annex I (normative) Test method for determining balloon size deflation reliability (catheter with non-compliant balloon)	27
Annex J (normative) Test method for determining inflated balloon resistance to traction	29

Bibliography	33
---------------------------	-----------

This document is a preview generated by EVS

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This document is based on EN 1616, *Sterile urethral catheters for single use*.

This corrected version of ISO 20696:2018 incorporates the following corrections:

- in Figure A.1, key items 1 and 2 were inverted.

Introduction

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

This document is a preview generated by EVS

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.