

STN	Sterilné uretrálne katétre na jednorazové použitie (ISO 20696: 2018)	STN EN ISO 20696
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Sterile urethral catheters for single use (ISO 20696:2018)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola označená vo Vestníku ÚNMS SR č. 12/18

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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)

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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.

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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.

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Sterile urethral catheters for single use

Sondes urinaires stériles non réutilisables



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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).

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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:

- correction of measurements and units in [5.5.2](#), [6.4.3](#), [6.9](#) and [J.2.1](#);
- deletion of EN 980 from Bibliography;
- minor editorial changes.

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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