SLOVENSKI STANDARD
SIST EN ISO 20697:2018

01-september-2018

Nadomešča:
SIST EN 1617:2000

Sterilni drenažni katetri in dodatni pripomočki za enkratno uporabo (ISO 20697:2018)

Sterile drainage catheters and accessory devices for single use (ISO 20697:2018)

Sterile Drainagekatheter und Zubehör zur einmaligen Verwendung (ISO 20697:2018)

Sondes et dispositifs auxiliaires stériles de drainage non réutilisables (ISO 20697:2018)

Ta slovenski standard je istoveten z: EN ISO 20697:2018

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 20697:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Sterile drainage catheters and accessory devices for single use (ISO 20697:2018)

Sondes et dispositifs auxiliaires stériles de drainage non réutilisables (ISO 20697:2018)

Sterile Drainagekatheter und Zubehör zur einmaligen Verwendung (ISO 20697:2018)

This European Standard was approved by CEN on 3 May 2018.

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

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European foreword

This document (EN ISO 20697:2018) 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of an identical text or by endorsement, at the latest by January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.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.

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Endorsement notice

The text of ISO 20697:2018 has been approved by CEN as EN ISO 20697:2018 without any modification.

INTERNATIONAL STANDARD

ISO 20697

First edition
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Sterile drainage catheters and accessory devices for single use

Sondes et dispositifs auxiliaires stériles de drainage 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 1617, *Sterile drainage catheters for single use*.

Introduction

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

Sterile drainage catheters and accessory devices for single use

1 Scope

This document specifies requirements for sterile, single use drainage catheters, wound and fluid accumulation drainage systems, surgical drainage catheters and their components, where the catheter is placed in a body cavity or wound, surgically or percutaneously, for drainage of fluid or air to the exterior.

The drainage catheter is left to drain naturally or connected to a suction source for faster tissue granulation.

This document is not applicable to:

a) suction catheters;

b) tracheal catheters;

c) urethral catheters;

NOTE See ISO 20696.

d) ureteral stents, biliary stents, and other stents;

NOTE See ISO 14630 and ASTM F1828-97 for stents requirements.

e) drainage catheters placed in digestive tracts percutaneously with gastrostomy technique;

f) neuraxial catheters used for removal of cerebrospinal fluid;

NOTE See ISO 20698.

g) enteral catheters used for removal of solutions or substances from the gastrointestinal tract;

NOTE See ISO 20695.

h) coatings.

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

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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.

