SLOVENSKI STANDARD
oSIST prEN ISO 20696:2017

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Sterilni uretralni katetri za enkratno uporabo (ISO/DIS 20696:2017)

Sterile urethral catheters for single use (ISO/DIS 20696:2017)

Sterile Harnblasenkatheter zur einmaligen Verwendung (ISO/DIS 20696:2017)

Sondes urinaires stériles non réutilisables (ISO/DIS 20696:2017)

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Sterile urethal catheters for single use

Titre manque

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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).

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 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.

The committee responsible for this document is Technical Committee ISO/TC 84, Devices for administration of medicinal products and catheters.

This is a new ISO standard based on European Standard EN 1616 *Sterile urethral catheters for single use*.

Introduction

Guidance on transition periods for implementing the requirements of this standard is given in ISO/TR 19244 'Guidance on transition periods for standards developed by ISO/TC 84 - Devices for administration of medicinal products and catheters'.

Sterile urethal catheters for single use

1 Scope

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

This standard does not include drainage catheters covered by ISO 20697 *Sterile Drainage catheters for single use* — e.g. ureteral catheters, nephrostomy catheters, and suprapubic catheters. This standard also excludes ureteral stents.

NOTE Ureteral stents are covered in ASTM F1828-97 Standard Specification for ureteral stents.

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

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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 http://www.iso.org/obp

— IEC Electropedia: available at http://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

3.5
effective shaft length (L_3)
length of non-perforated portion of the catheter excluding the tip, balloon(s), *funnel*(s) (3.6), protective sleeves and/or access port(s)

3.6
funnel
(proximal) portion of the catheter, which may be connected to a drainage system

Note 1 to entry: See Figure J.1, 2

3.7
intermittent
intended to be removed immediately after emptying the bladder

3.8
non-compliant balloon
balloon that expands to one specific size or size range, even as internal pressure increases

3.9
outer diameter
maximum dimension measured across the cylindrical portion of the shaft

3.10
overall length[L_1]
total length from the tip of the catheter to the end of the *funnel* (3.6) (connector)

3.11
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007, 2.16]

3.12
risk analysis
systematic use of available information to identify hazards and to estimate the *risk* (3.11)

Note 1 to entry: Risk analysis includes examination of different sequences of events that can produce hazardous situations and harm (see Annex F and ISO 14971:2007, Annex E).

[SOURCE: ISO 14971:2007, 2.17]

3.13
risk assessment
overall process comprising a *risk analysis* (3.12) and a risk evaluation

[SOURCE: ISO 14971:2007, 2.18]

3.14
risk management file
set of records and other documents that are produced by risk management

[SOURCE: ISO 14971:2007, 2.23]

3.15
urethral catheter
tubular device intended for being introduced into the urinary bladder through the urethra in order to provide drainage, drug delivery and/or flushing of the bladder

4 Intended performance

The urethral catheter shall demonstrate the ability to accurately, and safely access the intended location.

5 General requirements

5.1 Risk management

An established risk management process shall be applied to the design of the device.

EXAMPLE ISO 14971.

Compliance shall be checked by inspection of the risk management file. If clinical studies are performed, these studies shall document measurements taken under conditions for which performance is claimed. The clinical studies shall comply with the requirements of ISO 14155.

5.2 Biocompatibility

The device shall be free from biological hazard in accordance with appropriate testing under ISO 10993-1.

5.3 Detectability

The catheter or at least its effective length shall be detectable by X-ray or by other means (Ultra-sound, MRI, etc.), if required by the risk assessment.

5.4 Surface finish

When examined by normal or corrected to normal vision, the external surface of the effective length of the catheter shall appear free from:

— extraneous matter

— process and surface defects that may present an unacceptable risk of patient harm.

If deemed necessary based on risk assessment, inspection shall be conducted under a minimum 2,5X magnification.

5.5 Size designation

5.5.1 General

The nominal size of the catheter shall be designated as specified in 5.5.1 and 5.5.2.

5.5.2 Outer Diameter

Unless otherwise specified in another part of this document for a particular type of catheter, the outer diameter shall be expressed as the nominal dimension in mm, rounded upwards to the nearest 0,1 mm. Tolerances on this stated size shall be ±0,33 mm.

NOTE 1 Additional units can also be given.

For devices which are not round by design, the size shall be designated by the dimension of the largest axis. Where relevant, manufacturers may choose to report additional information regarding the device profile, such as the dimension of the second axis for an oval shape.

NOTE 2 French size (Fr, Ch, FG) is a nominal dimensional identification of the outer size of drainage catheters; calculated as three times the diameter (in millimetres): Fr = 3 x D (mm).The balloon capacity shall be expressed in ml.

5.5.3 Effective shaft lengths

The minimum effective shaft lengths (L_3) shall be as given in Table 1 (see also Figure 1).

The nominal effective shaft length (L_3) shall be expressed in mm, rounded to the nearest mm.

NOTE 1 Additional units can also be given.

NOTE 2 Tolerances to the effective length are not specified.

Table 1 — Effective shaft length

Catheter type	L_3 (minimum) mm
Paediatric male	150
Paediatric female	45
Female	60
Male	275
NOTE Shaft dimensions: Shorter sizes can be produced using appropriate risk based clinical justification.	

