SLOVENSKI STANDARD
SIST EN ISO 10555-4:2000

01-januar-2000

Sterilni žilni katetri za enkratno uporabo - 4. del: Balonski katetri za širjenje žil (ISO 10555-4:1996)

Sterile, single-use intravascular catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:1996)

Sterile intravaskuläre Katheter zur einmaligen Verwendung - Teil 4: Ballondilatationskatheter (ISO 10555-4:1996)

Cathéters intravasculaires stériles, non réutilisables - Partie 4: Cathéters de dilatation a ballonnets (ISO 10555-4:1996)

Ta slovenski standard je istoveten z: **EN ISO 10555-4:1997**

ICS:

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

SIST EN ISO 10555-4:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 10555-4

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English version

Sterile, single-use intravascular catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:1996)

Cathéters intravasculaires stériles, non réutilisables - Partie 4: Cathéters de dilatation à ballonnets (ISO 10555-4:1996)

Sterile intravaskuläre Katheter zur einmaligen Verwendung - Teil 4: Ballondilatationskatheter (ISO 10555-4:1996)

This European Standard was approved by CEN on 1997-06-09. 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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 84 "Medical devices for injections" of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

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 1998, and conflicting national standards shall be withdrawn at the latest by January 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10555-4:1996 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 594-1	1986	Conical fittings with à 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	EN 20594-1	1993
ISO 10555-1	1995	Sterile, single use, intravascular catheters - Part 1: General requirements	EN ISO 10555-1	1996

INTERNATIONAL STANDARD

ISO 10555-4

First edition
1996-06-15

Sterile, single-use intravascular catheters —

Part 4:
Balloon dilatation catheters

Cathéters intravasculaires stériles, non réutilisables —

Partie 4: Cathéters de dilatation à ballonnets

Reference number
ISO 10555-4:1996(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10555-4 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

ISO 10555 consists of the following parts, under the general title *Sterile, single-use intravascular catheters*:

— *Part 1: General requirements*

— *Part 2: Angiographic catheters*

— *Part 3: Central venous catheters*

— *Part 4: Balloon dilatation catheters*

— *Part 5: Over-needle peripheral catheters*

Annex A forms an integral part of this part of ISO 10555. Annexes B and C are for information only.

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Sterile, single-use intravascular catheters —

Part 4:
Balloon dilatation catheters

1 Scope

This part of ISO 10555 specifies requirements for balloon dilatation catheters supplied in the sterile condition, and intended for single use.

NOTE 1 Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

3 Definitions

For the purposes of this part of ISO 10555, the definitions given in ISO 10555-1 and the following definition apply.

3.1 balloon dilatation catheter: Intravascular catheter fitted with a balloon near the distal end, which is introduced into an artery or vein to dilate a part or parts of the vascular system.

4 Requirements

4.1 General

Unless otherwise specified in this part of ISO 10555, catheters shall comply with ISO 10555-1.

4.2 Radio-detectability

The position of the balloon shall be radio-detectable when the catheter has been inserted into the body.

NOTE 2 At the time of publication of this part of ISO 10555, there is no acceptable, validated test method to determine radio-detectability. An approved test method for producing a value of radio-detectability will be established. Until that time, a manufacturer may label his product "radio-opaque" provided he can support this claim by demonstrating that he has an appropriate method for showing radio-opacity.

4.3 Designation of nominal size

The nominal size of the catheter shall be designated by the following:

a) the diameter(s) of the inflated balloon(s) or, for multidiameter balloon(s), the diameter of each portion;

b) the effective length of the balloon;

c) the effective length of the catheter;

d) the diameter of the largest guidewire that can be used with the catheter, if applicable.

4.4 Physical requirements

4.4.1 Tip configuration

In order to minimize trauma to vessels during use, the tip of the distal end should be smooth, rounded, tapered or similarly finished.