SLOVENSKI STANDARD
oSIST prEN ISO 10555-1:2011

01-december-2011

Sterilni žilni katetri za enkratno uporabo - 1. del: Splošne zahteve (ISO/DIS 10555-1:2011)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO/DIS 10555-1:2011)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO/DIS 10555-1:2011)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 1: Exigences généralesv (ISO/DIS 10555-1:2011)

Ta slovenski standard je istoveten z: **prEN ISO 10555-1 rev**

ICS:

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

oSIST prEN ISO 10555-1:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 10555-1 rev

September 2011

ICS 11.040.25

Will supersede EN ISO 10555-1:2009

English Version

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO/DIS 10555-1:2011)

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Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO/DIS 10555-1:2011)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (prEN ISO 10555-1:2011) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and intravascular catheters" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 10555-1:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO/DIS 10555-1:2011 has been approved by CEN as a prEN ISO 10555-1:2011 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 10555-1

ISO/TC **84** Secretariat: **DS**

Voting begins on **2011-09-29** Voting terminates on **2012-02-29**

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Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 1: Exigences générales

[Revision of first edition (ISO 10555-1:1995) and ISO 10555-1:1995/Amd.1:1999 and ISO 10555-1:1995/Amd.2:2004]

ICS 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 10555-1 was prepared by Technical Committee ISO/TC 84, Devices for administration of medicinal products and intravascular catheters.

This second edition cancels and replaces the first edition which has been technically revised.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters — Sterile and single-use 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*

Attention is drawn to ISO 11070, which will specify requirements for accessory devices for use with intravascular catheters.