Steriilsed ühekordselt kasutatavad intravaskulaarsed (soonesisesed) kateetrid. Osa 5: Üle nõela paigaldatavad perifeersed kateetrid

Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10555-5:1999 sisaldab Euroopa standardi EN ISO 10555-5:1997+AC:1999 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10555-5:1999 consists of the English text of the European standard EN ISO 10555-5:1997+AC:1999.
Standard on kinnitatud Eesti Standardikeskuse 12.12.1999 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 12.12.1999 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.20

kateetrid, meditsiiniaparatuur, pärast kasutamist hävitatavad vahendid, soontesüsteem, steriilne varustus, teave tarbijale, tehnilised andmed, testimine, tähistus

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-5

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Descriptors: see ISO document

English version

Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:1996)

Cathéters intravasculaires stériles, non réutilisables - Partie 5: Cathéters périphériques à aiguille interne (ISO 10555-5:1996)

Sterile intravaskuläre Katheter zur einmaligen Verwendung - Teil 5: Periphere Katheter mit innen liegender Kanüle (ISO 10555-5:1996)

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 10555-5:1996 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 9626	1991	Stainless steel needle tubing for the manufacture of medical devices	EN ISO 9626	1995
ISO 10555-1	1995	Sterile, single use, intravascular catheters - Part 1: General requirements	EN ISO 10555-1	1996

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English version
Version Française
Deutsche Fassung

Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:1996)

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This corrigendum becomes effective on 21 January 1999 for incorporation in the official German version of the EN.

Ce corrigendum prendra effet le 21 janvier 1999 pour incorporation dans la version allemande officielle de l'EN.

Die Berichtigung tritt am 21.Januar 1999 zur Einarbeitung in die offizielle Deutsche Fassung der EN in Kraft.

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

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

This correction only concerns the German version.

In clause 4.2, replace “Der Katheter muss im Röntgenbild erkennbar sein” with “es wird empfohlen, daß der Katheter im Röntgenbild erkennbar ist”.

Cette correction ne s’applique qu’à la version allemande.

Clause 4.2, remplacer : “Der Katheter muss im Röntgenbild erkennbar sein” par : “es wird empfohlen, daß der Katheter im Röntgenbild erkennbar ist”.

Diese Korrektur betrifft nur die deutsche Fassung.

Im Abschnitt 4.2, “Der Katheter muss im Röntgenbild erkennbar sein” ist durch “es wird empfohlen, daß der Katheter im Röntgenbild erkennbar ist” zu ersetzen.

INTERNATIONAL STANDARD

ISO 10555-5

First edition
1996-06-15

Sterile, single-use intravascular catheters — Part 5: Over-needle peripheral catheters

Cathéters intravasculaires stériles, non réutilisables — Partie 5: Cathéters périphériques à aiguille interne

Reference number
ISO 10555-5:1996(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 10555-5 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*

Annexes A and B form an integral part of this part of ISO 10555. Annexes C, D and E are for information only.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Sterile, single-use intravascular catheters —

Part 5:
Over-needle peripheral catheters

1 Scope

This part of ISO 10555 specifies requirements for over-the-needle peripheral intravascular catheters, intended for accessing the peripheral vascular system, 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 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*

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 definitions apply.

3.1 peripheral intravascular catheter: Catheter designed for the introduction or withdrawal of liquids or devices into or from the peripheral vascular system.

3.2 needle: Assembly comprising at least a needle tube attached to, and communicating with, a needle hub.

See figure 1.

3.3 needle tube: Rigid tube with one end sharpened to facilitate entry into body tissue.

3.4 needle hub: Fitting attached to the needle tube, providing communication with its bore.

3.5 vent fitting: Fixed or removable fitting permitting venting of air while restricting or preferably preventing the escape of blood.

3.6 catheter unit: Assembly comprising the catheter tube, catheter hub and any integral fittings.

See figure 1.

3.7 flashback: Blood flow into the needle hub.

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

It is recommended that catheters be radio-opaque.