SLOVENSKI STANDARD
SIST EN ISO 10555-1:2000

01-januar-2000

Sterilni žilni katetri za enkratno uporabo - 1. del: Splošne zahteve (ISO 10555-1:1995)

Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995)

Sterile intravaskuläre Katheter zur einmaligen Verwendung -Teil 1: Allgemeine Anforderungen (ISO 10555-1:1995)

Cathéters intravasculaires stériles, non réutilisables - Partie 1: Prescriptions générales (ISO 10555-1:1995)

Ta slovenski standard je istoveten z: **EN ISO 10555-1:1996**

ICS:

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

SIST EN ISO 10555-1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1

August 1996

ICS 11.040.20

Descriptors: See ISO document

English version

Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995)

Cathéters intravasculaires stériles, non réutilisables - Partie 1: Prescriptions générales (ISO 10555-1:1995)

Sterile intravaskuläre Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO 10555-1:1995)

This European Standard was approved by CEN on 1996-07-08. 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, 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

Ref. No. EN ISO 10555-1:1996 E

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 February 1997, and conflicting national standards shall be withdrawn at the latest by January 1998.

This European Standard 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 Directives(s).

For relationship with EU Directive(s), see informative Annex ZB, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 10555-1:1996 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 a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	EN 20594-1	1993

Annex ZB (informative)

Clauses of this European Standard addresssing essential requirements or other provisions of the EU Directive

This standard has been prepared under a mandate given to CEN by the European Commission and the European Fre Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC:
See table ZB.1.

Compliance with the clauses of this standard provides one means of conforming with the relevant essential reqirements of the Directive concerned and associated EFTA Regulations.

TABLE ZB.1: Correspondence between clauses of this European Standard and the essential requiremnts of EU Directives

Clause/subclause of this European Standard	Corresponding essential requirement of Directive 93/42/EEC	Comments
4	1, 2, 3, 4, 5	
4.1	6, 7.2, 8.1	
4.2	6, 7.1, 7.5	
4.4	6, 7.3	
4.6	6, 7.6	
4.7	9.1	
5	1, 3, 9.2	
6	3, 13.1, 13.4	
6 a)	13.3 b)	
6 d)	13.3 a)	
6 e)	13.3 d)	
6 f)	13.3 e)	
6 g)	5	
6 h)	13.3 c)	
6 i)	13.3 m)	
6 j)	13.3 f)	
6 k)	13.3 k)	
6 l)	7.3, 13.1, 13.3 i), 13.3 j), 13.3 k), 13.4, 13.6 a), 13.6 b), 13.6 g)	
Annex A	1, 2, 3, 4, 5	
Annex B	1, 2, 3, 4, 5	
Annex C	1, 2, 3, 4, 5, 7.6	
Annex D	1, 2, 3, 4, 5, 7.6	

N/A = not applicable

INTERNATIONAL STANDARD

ISO 10555-1

First edition
1995-06-15

Sterile, single-use intravascular catheters —

Part 1:
General requirements

Cathéters intravasculaires stériles, non réutilisables —
Partie 1: Prescriptions générales

Reference number
ISO 10555-1:1995(E)

Contents

International Organization for Standardization
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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.

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 10555-1 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*

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

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