EESTI STANDARD EVS-EN ISO 9626:1999

Roostevabast terasest nõelatorud meditsiinivahendite tootmiseks

Stainless steel needle tubing for the manufacture of medical devices

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 9626:1999 sisaldab Euroopa standardi EN ISO 9626:1995 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 9626:1999 consists of the English text of the European standard EN ISO 9626:1995.
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.

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English version

Stainless steel needle tubing for the manufacture of medical devices (ISO 9626:1991)

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical (ISO 9626:1991)

Kanülenrohre aus nichtrostendem Stahl zur Herstellung von Medizinprodukten (ISO 9626:1991)

This European Standard was approved by CEN on 1994-11-14. 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

Foreword

This European Standard has been taken over by the Technical Committee CEN/TC 205 "Non-active medical devices" from the work of ISO/TC "Medical devices for injections" of the International Organization for Standardization (ISO).

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 August 1995, and conflicting national standards shall be withdrawn at the latest by August 1995.

According to the CEN/CENELEC Internal Regulations, 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, United Kingdom.

Endorsement notice

The text of the International Standard ISO 9626:1991 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 9626

First edition
1991-09-01

Stainless steel needle tubing for manufacture of medical devices

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical

Reference number
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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 9626 was prepared by Technical Committee ISO/TC 84, *Syringes for medical use and needles for injections*, Sub-Committee SC 1, *Syringes and needles for single use*.

Annexes A, B, C, D and E form an integral part of this International Standard.

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Stainless steel needle tubing for manufacture of medical devices

1 Scope

This International Standard specifies the dimensions, surface and mechanical properties of normal- and thin-walled tubing of designated metric sizes 3,4 mm to 0,3 mm, and of extra-thin-walled tubing of designated metric sizes 2,1 mm to 0,8 mm.

Because no data are available, this International Standard does not specify stiffness properties for extra-thin-walled tubing of designated metric sizes 0,8 mm; 0,9 mm; 1,2 mm; 1,4 mm; 1,8 mm and 2,1 mm.

This International Standard applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this International Standard. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in this International Standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard 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 683-13:1986, *Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

3 Materials

Tubing shall be made from austenitic stainless steel of types 10, 11, 16, 20, 21 or 23 in accordance with ISO 683-13.

4 Surface finish

When examined by normal or corrected vision, the outside surface of the tubing shall be smooth and free from defects.

5 Cleanliness

When examined by normal or corrected vision, the surfaces of the tubing shall be free from metal soil and processing agents.

6 Limits for acidity and alkalinity

When tested in accordance with annex A, an extract of the tubing prepared in accordance with annex B shall, when corrected for the volume of titrant required for the control fluid, require not more than 0,04 ml of sodium hydroxide solution or not more than 0,12 ml of hydrochloric acid solution to reach the end-point of the titration.

7 Size designation

Tubing shall be designated by the nominal outside diameter expressed in millimetres (i.e. the designated metric size) and by its category, i.e. normal-walled, thin-walled, or extra-thin-walled.