SLOVENSKI STANDARD
SIST EN ISO 9626:2000/A1:2002

01-maj-2002

Igle iz nerjavnega jekla za izdelavo medicinskih pripomoļ kov (ISO 9626:1991/AM1:2001)

Stainless steel needle tubing for the manufacture of medical devices (ISO 9626:1991/AM 1:2001)

Edelstahlrohr zur Herstellung von Medizinprodukten (ISO 9626:1991/AM 1:2001)

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical (ISO 9626:1991/AM 1:2001)

Ta slovenski standard je istoveten z: **EN ISO 9626:1995/A1:2001**

ICS:

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

SIST EN ISO 9626:2000/A1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9626:1995/A1

June 2001

ICS 11.040.20

English version

Stainless steel needle tubing for the manufacture of medical devices (ISO 9626:1991/AM 1:2001)

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical (ISO 9626:1991/AM 1:2001)

Edelstahlrohr zur Herstellung von Medizinprodukten (ISO 9626:1991/AM 1:2001)

This amendment A1 modifies the European Standard EN ISO 9626:1995; it was approved by CEN on 1 June 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This amendment exists 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 Management Centre 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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

Corrected 2001-12-12

The text of this Amendment EN ISO 9626:1995/A1:2001 to the EN ISO 9626:1995 has been prepared by Technical Committee ISO/TC 84 "Medical devices for injections" in collaboration with 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 December 2001, and conflicting national standards shall be withdrawn at the latest by December 2001.

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 Amendment to the International Standard ISO 9626:1991/AM 1:2001 has been approved by CEN as an Amendment to the 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 (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995

INTERNATIONAL STANDARD

ISO 9626

First edition
1991-09-01

AMENDMENT 1
2001-06-01

Stainless steel needle tubing for the manufacture of medical devices —

AMENDMENT 1

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

AMENDEMENT 1

Reference number
ISO 9626:1991/Amd.1:2001(E)

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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 3.

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 Amendment may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to International Standard ISO 9626:1991 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.