SLOVENSKI STANDARD
SIST EN ISO 595-2:2000

01-januar-2000

Injekcijske brizge iz stekla ali kovine in stekla za veļ kratno uporabo v medicini - 2. del: Zasnova, zahteve za kakovost in preskusi (ISO 595-2:1987)

Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements and tests (ISO 595-2:1987)

Wiederverwendbare medizinische Glasspritzen oder Spritzen aus Glas und Metall - Teil 2: Konstruktion, Anforderungen an die Funktion und Prüfungen (ISO 595-2:1987)

Seringues réutilisables en verre ou en verre et métal a usage médical - Partie 2: Conception, performances et essais (ISO 595-2:1987)

Ta slovenski standard je istoveten z: **EN ISO 595-2:1994**

ICS:

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

SIST EN ISO 595-2:2000 **en**

EUROPEAN STANDARD

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English version

Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements and tests (ISO 595-2:1987)

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This European Standard was approved by CEN on 1994-08-09. 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.

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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 84 "Transfusion, infusion and injection equipment" 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of an identical text or by endorsement, at the latest by February 1995, and conflicting national standards shall be withdrawn at the latest by February 1995.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 595-2:1987 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications 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).

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

INTERNATIONAL STANDARD

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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Reusable all-glass or metal-and-glass syringes for medical use —

Part 2: Design, performance requirements and tests

Seringues réutilisables en verre ou en verre et métal à usage médical —

Partie 2: Conception, performances et essais

Reference number
ISO 595-2 : 1987 (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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 595-2 was prepared by Technical Committee ISO/TC 84, *Syringes for medical use and needles for injections*.

Together with ISO 595-1 : 1986 it cancels and replaces ISO Recommendation R 595 : 1967, of which it constitutes a technical revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Reusable all-glass or metal-and-glass syringes for medical use —

Part 2: Design, performance requirements and tests

0 Introduction

This International Standard on reusable syringes for medical use comprises two parts: ISO 595-1 covers the dimensions and details of the scale and ISO 595-2 (this part of ISO 595) covers design, performance and test methods.

1 Scope and field of application

This part of ISO 595 specifies the design, performance and the corresponding test methods for reusable syringes having a graduated capacity from 1 to 100 ml, for general medical use.

This part of ISO 595 is applicable to syringes of all-glass and metal-and-glass construction.

2 References

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*[1)]

3 Materials

3.1 Glass

Soda glass shall not be used for the manufacture of syringes.

3.2 Metal

If a metal part is protected by means of an electroplated or other type of coating, the base metal shall be capable of passing the test specified in 6.3 in the absence of the coating.

4 Construction and assembly

4.1 General

4.1.1 The construction shall be such that the piston is completely removable from the barrel.

4.1.2 The nozzle shall be a male conical fitting with a 6 % (Luer) taper in accordance with ISO 594-1 and/or ISO 594-2.

4.1.3 On syringes having a capacity up to 2 ml, the nozzle shall be situated centrally on the barrel. On syringes having a capacity above 2 ml, the nozzle shall be situated either centrally or eccentrically on the barrel.

If the nozzle is situated eccentrically, the distance between the axis of the nozzle and the nearest point of the internal surface of the barrel shall be not greater than 4 mm and the nozzle axis shall be diametrically opposite the scale on the barrel.

4.1.4 In all cases, the axis of the nozzle shall be parallel with the axis of the barrel.

4.1.5 The bore of the nozzle shall be centrally situated in the nozzle.

4.1.6 A means of braking the piston shall be provided unless the barrel and packaging are marked to indicate that no means of braking is provided.

If a means of braking the piston is provided, it shall be such that when the syringe is held in a vertical position with the nozzle uppermost, the piston shall remain stationary and shall not slide down under its own weight.

The braking action shall be such as not to interfere unduly with the operation of the piston in the syringe.

1) At present at the stage of draft.