



# SLOVENSKI STANDARD SIST EN 1707:2000

01-januar-2000

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]b`bY\_UHfc`Xfi [c`a YX]Wbg`c`cdfYa c`!Gdc^\_Y

Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings

Kegelverbindungen mit einem 6 % (Luer) Kegel für Spritzen, Kanülen und bestimmte andere medizinische Geräte - Verriegelbare Kegelverbindungen

Assemblages coniques a 6 % (Luer) des seringues et aiguilles et de certains autres appareils a usage médical - Assemblages a verrouillage

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Ta slovenski standard je istoveten z: EN 1707:1996

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## ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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en

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ICS 11.040.20

Descriptors: medical equipment, syringes, surgical needles, joining, fittings, conical components, locking devices, dimensions, dimensional tolerances, specifications, tests

English version

### Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings

Assemblages coniques à 6 % (Luer) des seringues et aiguilles et de certains autres appareils à usage médical - Assemblages à verrouillage

Kegelverbindungen mit einem 6 % (Luer) Kegel für Spritzen, Kanülen und bestimmte andere medizinische Geräte - Verriegelbare Kegelverbindungen

This European Standard was approved by CEN on 1996-10-19. 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

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## Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by BSI.

This European Standard applies to conical lock fittings with a 6 % (Luer) taper for use in medical equipment. EN 20594-1 addresses general requirements for taper fittings.

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 May 1997, and conflicting national standards shall be withdrawn at the latest by May 1997.

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 Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, 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.

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## 1 Scope

This European Standard specifies requirements for conical lock fittings with a 6 % (Luer) taper for use with hypodermic syringes and needles and with certain other apparatus for medical use e.g. transfusion equipment.

The requirements apply to fittings made of rigid and of semi-rigid materials and include test methods, but exclude provision for more flexible or elastomeric materials.

NOTE 1. It is not practicable to define the characteristics of rigid or semi-rigid materials with precision, but glass and metal may be considered as typical rigid materials. In contrast many plastics materials may be regarded as semi-rigid.

NOTE 2. The Luer lock fitting was designed for use at pressures of the order of 300 kPa or lower. Its use in other applications may require consideration to establish its suitability.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate place 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.

- |                   |  |
|-------------------|--|
| ISO 468           | Surface roughness - Parameters, their values and general rules for specifying requirements   |
| EN 20594-1: 1993  | Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986) |
| ISO 7886-1 : 1993 | Sterile hypodermic syringes for single use - Part 1: Syringes for manual use   |
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### 3 Dimensions and tolerances

#### 3.1 Male and female 6 % (Luer) conical fittings

The dimensions and tolerances for the male and female fittings specified in EN 20594-1 apply to the relevant conical part of the fitting described in clause 4 of this European Standard.

#### 3.2 Male and female 6 % (Luer) conical lock fittings

##### 3.2.1 Rigid materials

The dimensions of male and female lock fittings made of rigid materials shall be as shown in figures 1 to 4 and as given in table 1.

##### 3.2.2 Semi-rigid materials

For fittings made using semi-rigid materials, because of their nature, it is not possible to specify the fittings dimensions accurately. Design and dimensions of fittings made of these materials may vary from those designated in figures 1 and 4 and given in table 1. However, the fittings shall meet the specified performance requirements when fitted to reference fittings as specified in 5.1.

### 4 Requirements

#### 4.1 Gauging

When tested with the appropriate gauge, the conical part of the lock fitting shall comply with EN 20594-1.

#### 4.2 Leakage

##### 4.2.1 Liquid leakage

When the fitting is tested in accordance with 5.2, there shall be no leakage sufficient to form a falling drop.

##### 4.2.2 Air leakage

When the fitting is tested in accordance with 5.3, there shall be no signs of continued formation of air bubbles. Bubbles formed during the first 5 s shall be disregarded.

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#### **4.3 Separation force**

When the fitting is tested in accordance with 5.4, it shall remain attached to the reference fitting.

#### **4.4 Unscrewing torque**

When the fitting is tested in accordance with 5.5, it shall remain attached to the reference fitting.

#### **4.5 Ease of assembly**

When the fitting under test is mounted by hand on the appropriate reference fitting in accordance with 5.6, the following criterion, as appropriate, shall be satisfied:

- a) rigid fittings: no resistance shall be observed until the taper of the fitting under test and the reference fitting fit together securely;
- b) semi-rigid fittings: a satisfactory fit shall be achieved by applying an axial force not exceeding 20 N while applying a torque not exceeding 0,08 Nm.

#### **4.6 Resistance to overriding**

When the fitting is tested in accordance with 5.7, the reference fitting shall not override the threads or lugs of the fitting under test.

#### **4.7 Stress cracking**

When the fitting is tested in accordance with 5.8, there shall be no evidence of stress cracking of the fitting.

NOTE. Materials used for fittings should be resistant to stress cracking in environments likely to be encountered in use (e.g. when in contact with solvents, surface active agents, etc.).

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## 5 Test methods

### 5.1 General

Tests shall be carried out using the appropriate reference fitting; reference fittings are shown in figures 5 to 8. The reference fittings shall be manufactured from hardened corrosion-resistant materials with a surface roughness value,  $R_a$ , not exceeding  $0,8 \mu\text{m}$  (in accordance with ISO 468) on critical surfaces. The dimensions of the conical part of these reference fittings shall be in accordance with those specified in figures 4 and 5 of EN 20594-1:1993.

### 5.2 Liquid leakage from fitting assembly under pressure

**5.2.1** Connect the fitting to be tested to a reference fitting, the dimensions of which are in accordance with those shown in figures 5 or 7, as appropriate. Dry both fittings. Assemble the fittings by applying an axial force not exceeding 27,5 N while applying a torque not exceeding 0,12 Nm.

**5.2.2** Introduce water into the assembly and expel the air. Ensure that the outside of the fitting assembly is dry.

**5.2.3** With the axis of the lock fitting horizontal, seal the assembly outlet and bring the internal water pressure to an effective pressure of 300 kPa to 330 kPa and maintain the pressure for 30 s.

If the intended use is on a device employing higher pressure, then this shall be taken into consideration during testing.

### 5.3 Air leakage into fitting assembly during aspiration

#### 5.3.1 *General*

Other validated test methods (e.g. methods involving automatic testing) may be used if good correlation is shown with the reference test given in 5.3.2 or 5.3.3. In cases of dispute, the methods given in this European Standard shall be the referee methods.

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#### 5.3.2 *Male fitting*

**5.3.2.1** Connect the male fitting to a female reference fitting, the dimensions of which are in accordance with those shown in figure 5. Dry both fittings. Connect the male fitting to the female reference fitting by applying an axial force not exceeding 27,5 N while applying a torque not exceeding 0,12 Nm.

**5.3.2.2** Connect the female reference fitting, via a leakproof joint of minimal volume, to a syringe which has passed the test for leakage past the piston during aspiration in accordance with ISO 7886-1.

**5.3.2.3** Draw into the syringe, through the assembly, a volume of recently boiled and cooled water exceeding 25 % of the graduated capacity of the syringe. Avoid wetting the outside of the assembly.

**5.3.2.4** Expel the air except for a small residual air bubble and adjust the volume of water in the syringe to 25 % of the graduated capacity.

**5.3.2.5** Occlude the device below the fitting assembly. With the nozzle of the syringe downwards, withdraw the plunger to nominal capacity and hold for 15 s.

### **5.3.3 Female fitting**

Follow the same test procedure as specified in 5.3.2, but using a syringe with a male reference fitting, the dimensions of which are in accordance with those shown in figure 7, to mate with the female fitting under test.

## **5.4 Separation force of fitting assembly**

**5.4.1** Connect the fitting to be tested to a reference fitting, the dimensions of which are in accordance with those shown in figure 6 or 8 as appropriate; follow the same assembly procedure as specified in 5.2.1 for liquid leakage testing.

**5.4.2** Apply an axial force progressively up to 35 N in a direction away from the test fixture. Apply the force at a rate of approximately 10 N/s and maintain it for not less than 10 s. Do not apply any force in other directions or any inertial loading.

## **5.5 Unscrewing torque of fitting assembly**

**5.5.1** Follow the same assembly procedure as specified in 5.4.1.

**5.5.2** Apply an unscrewing torque of  $(0,02 \pm_{0,002})$  Nm to the assembly and maintain for not less than 10 s. Do not apply any force in other directions or any inertial loading.

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**5.6 Ease of assembly**

Mount by hand the fitting under test on the male or female reference fitting (see figures 5 and 7) as appropriate. For rigid fittings, assemble the fittings securely; for semi-rigid fittings, apply an axial force not exceeding 20 N together with a torque not exceeding 0,08 Nm.

### **5.7 Resistance to overriding**

Follow the same procedure as specified in 5.2.1 for liquid leakage testing, but using the appropriate reference fitting shown in figure 6 or 8; apply a torque not less than 0,15 Nm to the fitting under test and hold constant for 5 s.

### **5.8 Stress cracking**

**5.8.1** Connect the fitting to be tested to a reference fitting, the dimensions of which are in accordance with those shown in figures 5 and 7, as appropriate. Dry both fittings. Assemble the fittings by applying an axial force not less than 27,5 N for 5 s while applying a torque not less than 0,12 Nm.

**5.8.2** Allow the fittings to remain assembled for  $(48 \pm 1)$  h at  $(20 \pm 5)$  °C.

NOTE. The use of  $(27 \pm 5)$  °C is accepted as an alternative to  $(20 \pm 5)$  °C for tropical countries.

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