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

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Swedish Standards corresponding to documents referred to in this Standard are listed in "Catalogue of Swedish Standards", issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Koniska kopplingar (Luer) för injektionssprutor, kanyler etc. - Luer-lock

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ICS 11.040.20

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Postadress: SIS, Box 6455, 113 82 STOCKHOLM
Telefon: 08 - 610 30 00. Telefax: 08 - 30 77 57

Upplysningar om **sakinnehållet** i standarden lämnas av HSS.
Telefon: 08 - 702 49 00. Telefax: 08 - 702 49 15
E-post: hss@hss.se
Prisgrupp N

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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.

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

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 leak 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.

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 [he 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 fittings is used 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 fittings 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 enviroments likely to be encountered in use (e.g. when in contact with solvents, surface active agents, etc.).

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.

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 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.

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

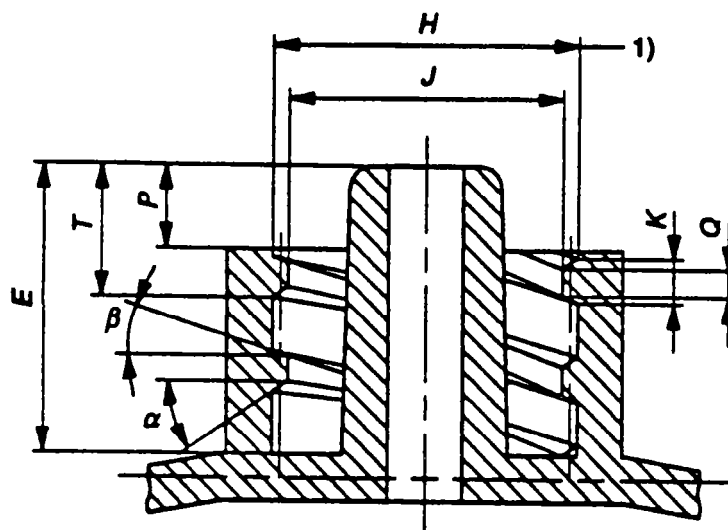
5.8.1 Connect the fitting to be tested to a reference fitting, the dimensions of which are in accordance with those shown in figures 5 and 7, as appropriate. Dry both fittings. Assemble the fittings by applying an axial force not less than 27,5 N for 5 s while applying a torque not less than 0,12 Nm,

5.8.2 Allow the fittings to remain assembled for (48 ± 1) h at (20 ± 5) °C.

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

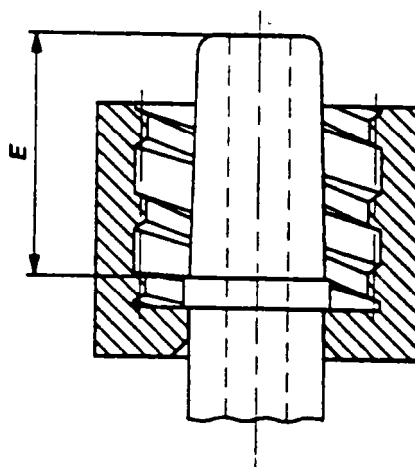
Dimensions in millimetres

Table 1: Dimensions of 6 % (Luer) rigid conical lock fittings			
Symbol	Designation	Dimension	
		Figures 1, 2, 3a and 4	Figure 3b and 3c
α	Angle of thread or lug bearing surface against separation with the plane perpendicular to the axis of lock fitting	$25^{\circ} \begin{smallmatrix} +5^{\circ} \\ 0^{\circ} \end{smallmatrix}$	$25^{\circ} \begin{smallmatrix} +5^{\circ} \\ 0^{\circ} \end{smallmatrix}$
β	Angle of internal thread non-bearing surface against separation with the plane perpendicular to the axis of lock fitting	25° min.	-----
γ	Angle of external thread or lug non-bearing surface against separation with the plane perpendicular to the axis of the lock fitting	0° min	0° min
E	Length of male lock fitting	7,5 min.	-----
F	Distance from the face of the fitting to the base of the lug	-----	0,20 nom.
G	Outside diameter of female lock fitting at base of lugs or inside diameter of external thread. This diameter shall not be increased for a distance from the hub face of 5,5 mm	6,73 max.	5,7 max.
H	Root diameter of the thread of male lock fitting	$8,0 \pm 0,1$	-----
J	Crest diameter of the thread of male lock fitting	$7,0 \pm 0,2$	-----
K	Thread width of male lock fitting at root	1 max.	-----
P	Projection of nozzle from collar	2,1 min.	-----
Q	Thread crest width of male lock fittings	0,3 min.	-----
S	Lug crest width or thread crest width of female lock fitting with lugs or external thread	0,3 min.	0,27 max.
T	Distance from tip of male lock fitting to the bottom of first complete thread form of the internal thread	3,2 max.	-----
V	Chord length at base of lug in a plane at right angles to axis of fitting only, to be measured on a chord of a circle the diameter of which is J min. (7,0 mm)	3,5 max.	5,0 max.
W	Chord length at extremity of lug in a plane at right angles to axis of fitting only (W shall not be greater than V)	2,71 min.	-----
X	Distance from axis of female lock fitting to extremity of lug	-----	-----
2X	Outside diameter across the lugs or external thread	$7,83 \begin{smallmatrix} 0 \\ -0,1 \end{smallmatrix}$	$7,80 \begin{smallmatrix} 0 \\ -0,1 \end{smallmatrix}$
Y	Width of base of lug (axial) or thread at base, of female lock fitting to be measured at a point corresponding to an outside diameter equal to G (6,73 max.)	1,2 max.	1,30 max.
Z	Width across the lugs at external thread	-----	$6,50 \begin{smallmatrix} 0 \\ -0,1 \end{smallmatrix}$
Pitch	Nominal pitch of double-start, right-hand thread of female lock fitting - 5 mm lead	2,5	-----



1) Double-start, right-hand thread of 2,5 mm pitch.

Figure 1. Male 6 % (Luer) conical lock fitting with permanently connected internally threaded collar



NOTE. For other dimensions, see figure 1.

Figure 2. Male 6 % (Luer) conical lock fitting with rotatable internally threaded collar

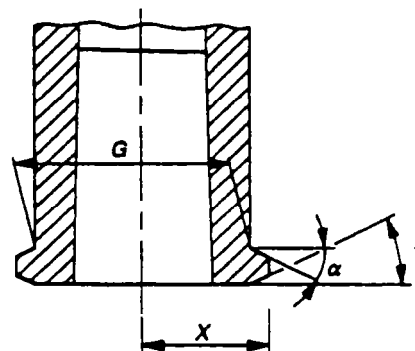
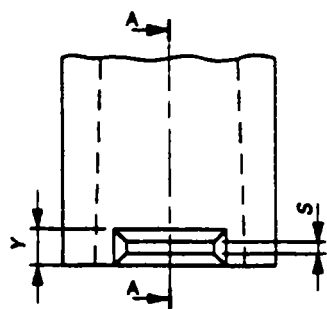
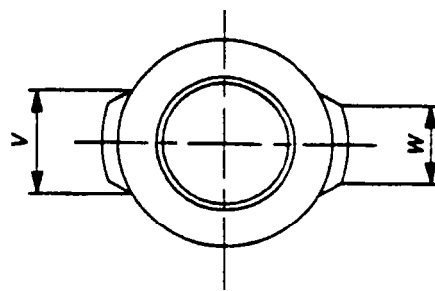


Figure 3a) Variant A

A - A

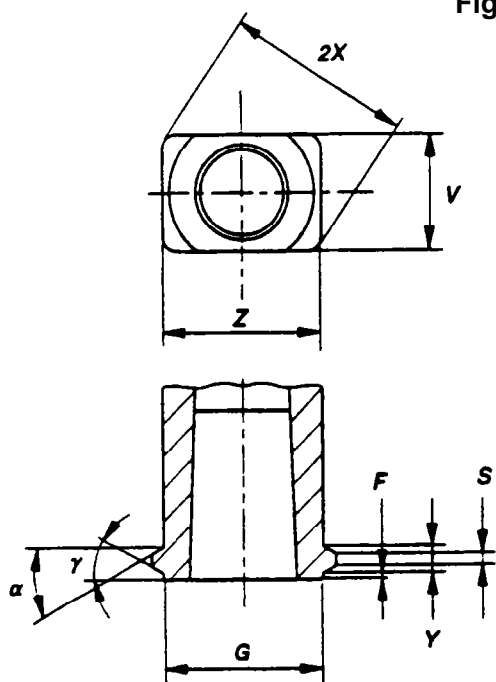


Figure 3b) Variant B

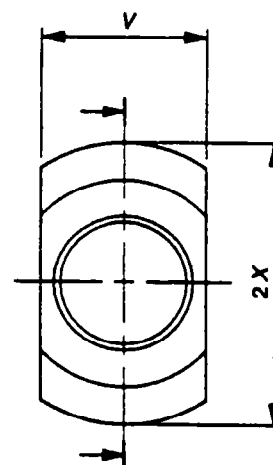


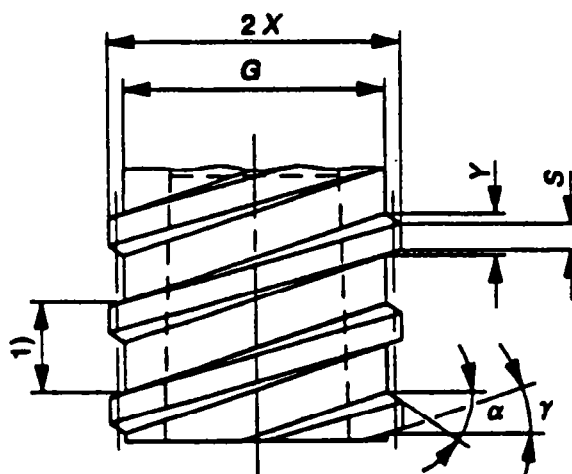
Figure 3c) Variant C

NOTE 1: If a female 6 % (Luer) conical lock fitting has lugs in a plane inclined to the axis of fitting, the lugs should form a part of the thread form shown in figure 4. In this case, 'V' does not apply.

NOTE 2: Variants B and C are intended to be used for the design of rigid fittings only.

NOTE 3: To ensure compatibility with existing rigid fittings $K = 0,8$ mm maximum is preferred.

Figure 3. Female 6 % (Luer) conical lock fittings with lugs in a plane at right angles to axis of fitting

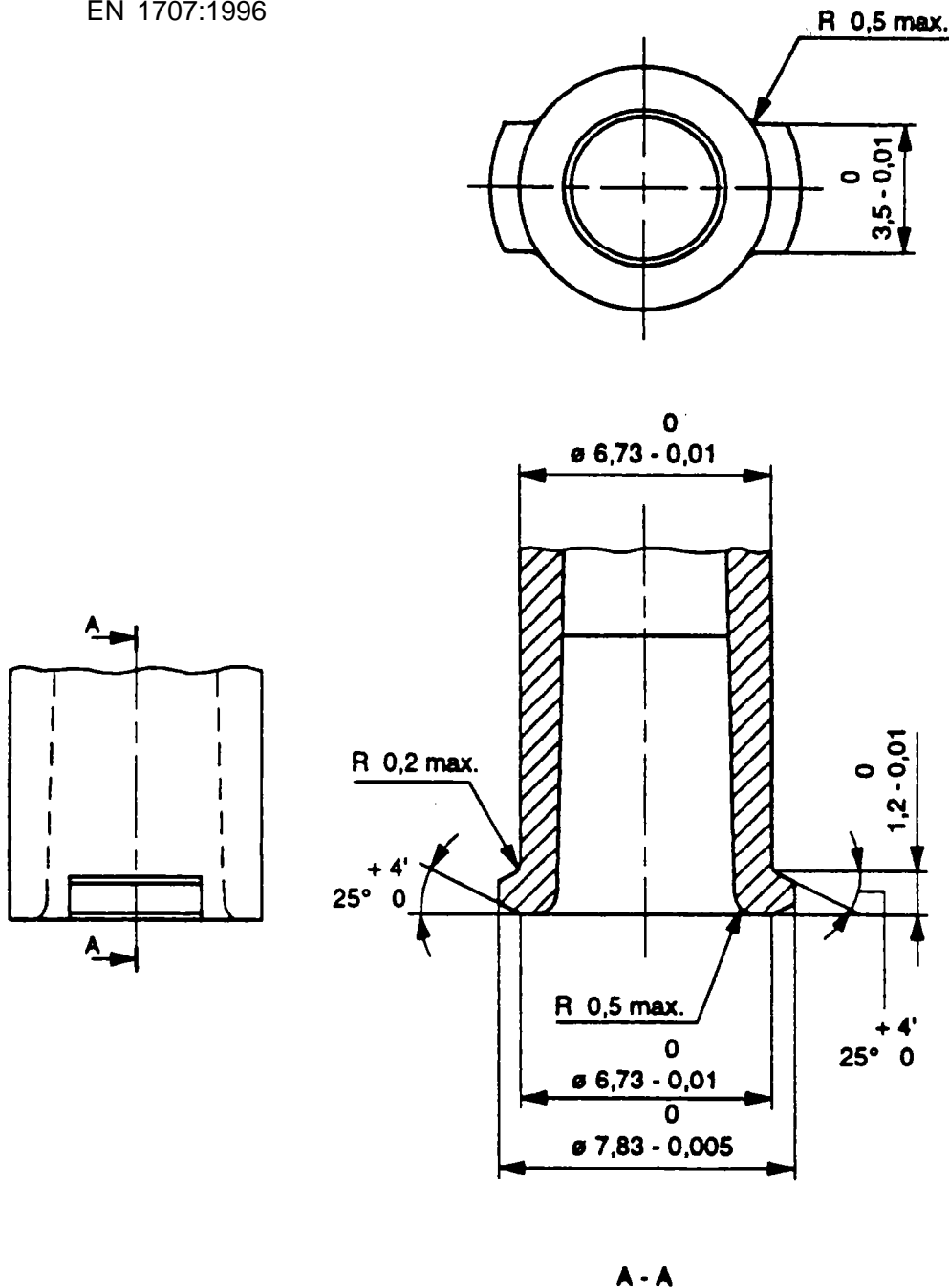


1) Pitch.

NOTE. For other dimensions, see figure 3.

Figure 4. Female 6 % (Luer) lock conical fitting with external thread

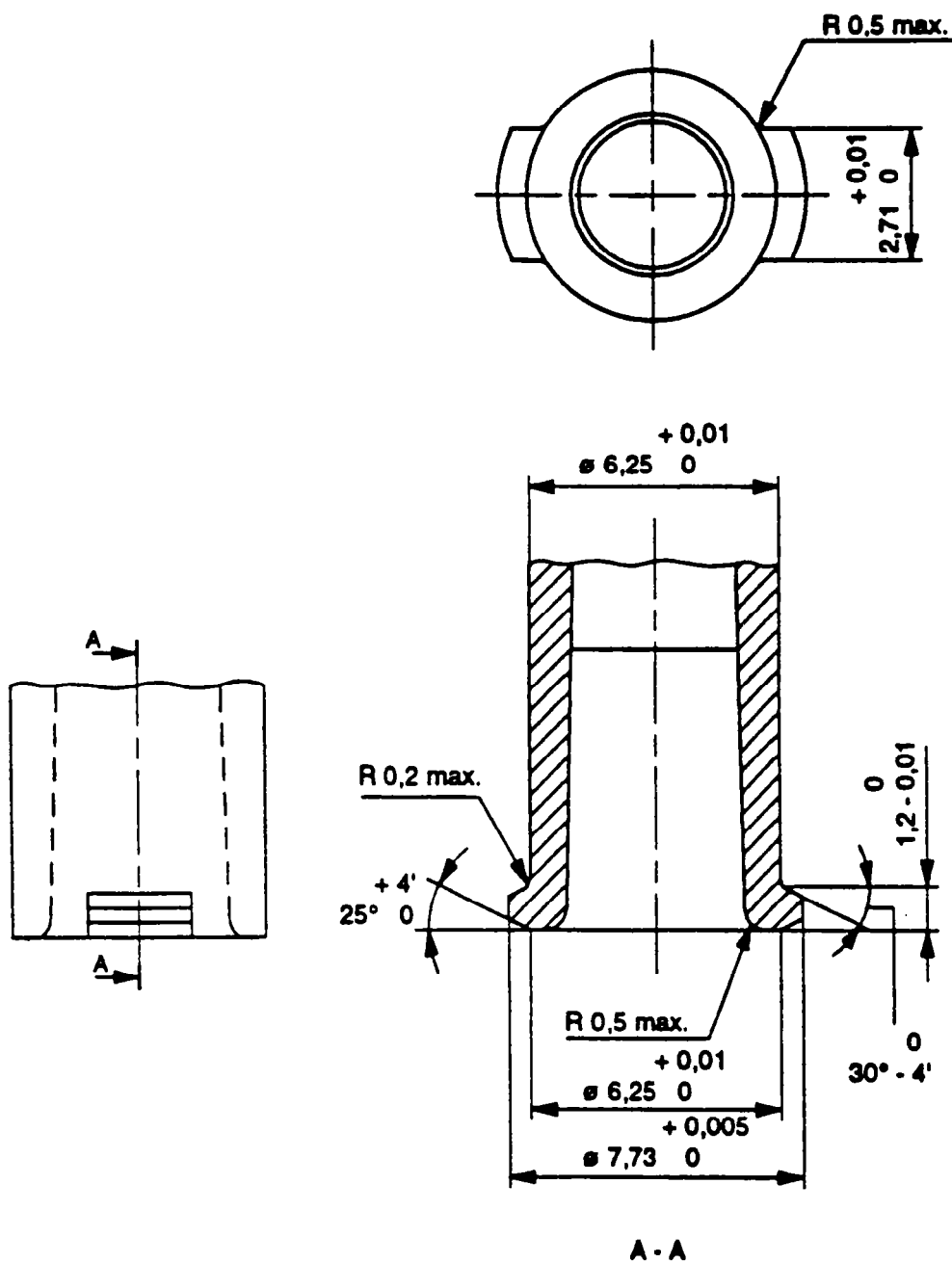
Dimensions in millimetres



NOTE. All outside edges of lug or thread form shall have a radius between 0,15 mm and 0,2 mm (unless otherwise specified).

Figure 5. Female reference conical fitting for testing male 6 % (Luer) lock fittings for leakage, ease of assembly, unscrewing torque and stress cracking (see 5.2, 5.3, 5.5, 5.6 and 5.8),

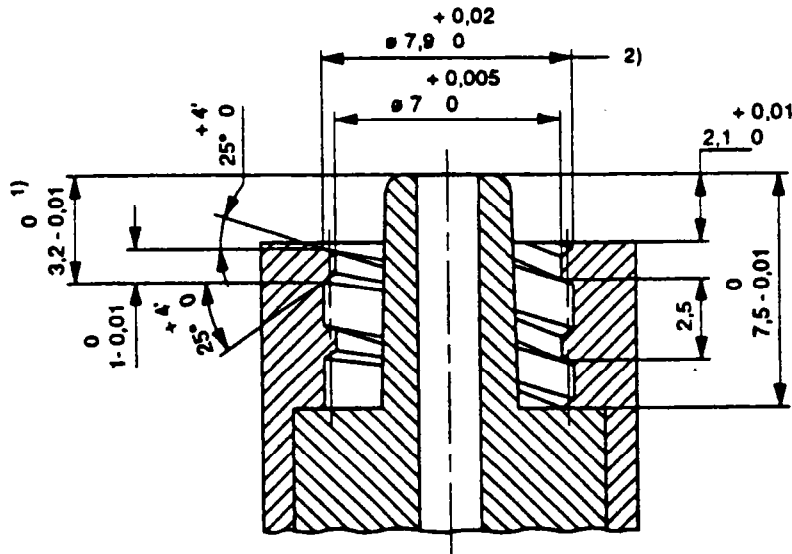
Dimensions in millimetres



NOTE. All outside edges of lug or thread form shall have a radius between 0,15 mm and 0,2 mm (unless otherwise specified).

Figure 6. Female reference conical fitting for testing male 6 % (Luer) lock fittings for separation force and resistance to overriding (see 5.4 and 5.7).

Dimensions in millimetres

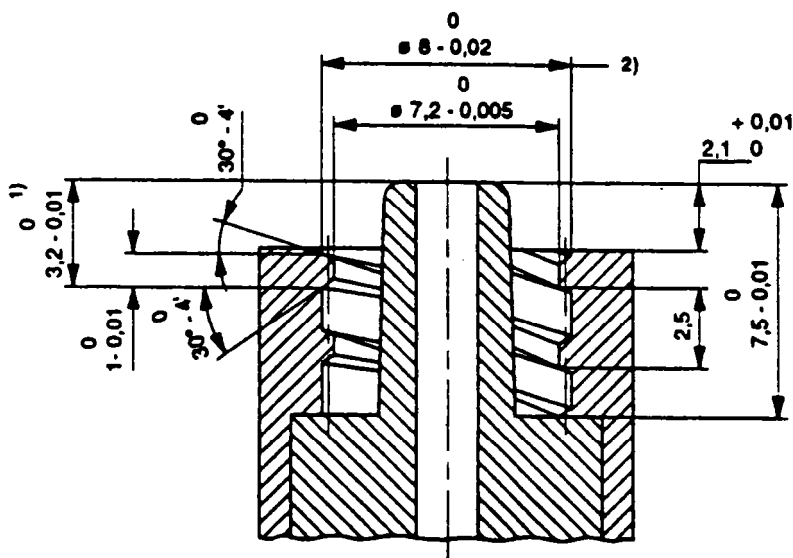


1) Maximum distance from tip of male lock fitting to the bottom of first complete thread form of the internal thread (see *Tin* table 1).

2) Double-start, right-hand thread of 2,5 mm pitch.

Figure 7. Male reference conical fitting for testing female 6 % (Luer) lock fittings for leakage, ease of assembly, unscrewing torque and stress cracking (see 5.2, 5.3, 5.5, 5.6 and 5.8)

Dimensions in millimetres



1) Maximum distance from tip of male lock fitting to the first complete thread form of the internal thread (see *Tin* table 1).

2) Double-start, right-hand thread of 2,5 mm pitch.

Figure 8. Male reference conical fitting for testing female 6 % (Luer) lock fittings for separation force and resistance to overriding (see 5.4 and 5.7)

Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free 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 clauses of this standard (see table 2A. 1) are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

TABLE ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
3	2, 3, 9.1	
4	2, 3, 7.6, 9.1	
4.2	7.5	
5	2, 3, 7.6, 9.1	
5.2	7.5	
5.3	7.5	

N/A = not applicable