



# SLOVENSKI STANDARD SIST EN 20594-1:2000

01-januar-2000

Glavni Uglavni gdc^Yg\*!cXglcHb]a fl@ Yf^j ]a LbUglUj \_ca `nU]b^Y\_W^g\_YVf]n[ YZ][ `Y ]b`bY\_UH^fc`Xfi [ c`a YX]W]bg\_c`cdfYa c`!`%`XY. Gd`cybY`nU H^j Y`fIGC`) - (!%%, \*Ł

Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986)

Kegelverbindungen mit einem 6% (Luer) Kegel für Spritzen, Kanülen und bestimmte andere medizinische Geräte - Teil 1: Allgemeine Anforderungen (ISO 594-1:1986)

Assemblages coniques a 6% (Luer) des seringues et aiguilles et de certains autres appareils a usage médical - Partie 1: Spécifications générales (ISO 594-1:1986)

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**Ta slovenski standard je istoveten z: EN 20594-1:1993**

**ICS:**

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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**SIST EN 20594-1:2000**

**en**

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EUROPEAN STANDARD

EN 20594-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 1993

UDC 615.473.36

Descriptors: Medical equipment, syringes, surgical needles, perfusion equipment, blood transfusion equipment, joining, fittings, specifications, dimensions, tests

English version

**Conical fittings with a 6% (Luer) taper for  
syringes, needles and certain other medical  
equipment - Part 1: General requirements  
(ISO 594-1:1986)**

Assemblages coniques à 6% (Luer) des seringues et aiguilles et de certains autres appareils à usage médical - Partie 1: Spécifications générales (ISO 594-1:1986)

Kegelverbindungen mit einem 6% (Luer) Kegel für Spritzen, Kanülen und bestimmte andere medizinische Geräte - Teil 1: Allgemeine Anforderungen (ISO 594-1:1986)

This European Standard was approved by CEN on 1993-08-12. 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.

**iTeh STANDARD PREVIEW**

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.

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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

In 1989, ISO 594-1:1986 "Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements" was submitted to the CEN Primary Questionnaire procedure.

Following the positive result of the CEN/CS Proposal ISO 594-1:1986 was submitted to the Formal Vote.

The result of the Formal Vote was positive.

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 1994, and conflicting national standards shall be withdrawn at the latest by February 1994.

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 594-1:1986 was approved by CEN as a European Standard without any modification.

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# International Standard



# 594 / 1

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

*Assemblages coniques à 6 % (Luer) des seringues et aiguilles et de certains autres appareils à usage médical —  
Partie 1: Spécifications générales*

First edition — 1986-06-15

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UDC 615.473.36

Ref. No. ISO 594/1-1986 (E)

**Descriptors** : medical equipment, syringes, hypodermic needles, fittings, conical clamping connections, specifications, dimensions, tests, pressure tests.

Price based on 7 pages

## 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 594/1 was prepared by Technical Committee ISO/TC 84, *Syringes for medical use and needles for injections*.

Together with ISO 594/2, it cancels and replaces ISO Recommendation R 594-1967, 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.

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

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## 0 Introduction

In this revision of ISO/R 594 first published in 1967, the opportunity has been taken to incorporate test methods for gauging and performance.

It should be noted that the annex does not form an integral part of the standard.

ISO 594/2 deals with lock fittings.

## 1 Scope and field of application

This part of ISO 594 specifies requirements for conical fittings with a 6 % (Luer) taper for use with hypodermic syringes and needles and with certain other apparatus for medical use such as transfusion and infusion sets.

It covers conical fittings made of rigid and of semi-rigid materials and includes test methods for gauging and performance. It excludes provision for more flexible or elastomeric materials.

Figure 1 illustrates typical male 6 % (Luer) conical fitting ("male fitting") and female 6 % (Luer) conical fitting ("female fitting").

NOTE — 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. By contrast, many plastic materials may be regarded as semi-rigid although the wall thickness is an important factor influencing the rigidity of a component.

## 2 References

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

ISO 7886, *Sterile hypodermic syringes for single use.*

## 3 Dimensions

The dimensions of male and female conical fittings shall be as given in the table and as shown in figure 1.

A typical assembly of 6 % (Luer) conical fittings is shown in figure 2.

The dimensions of the assembly shall be as given in the table.

1) At present at the stage of draft.

Dimensions in millimetres

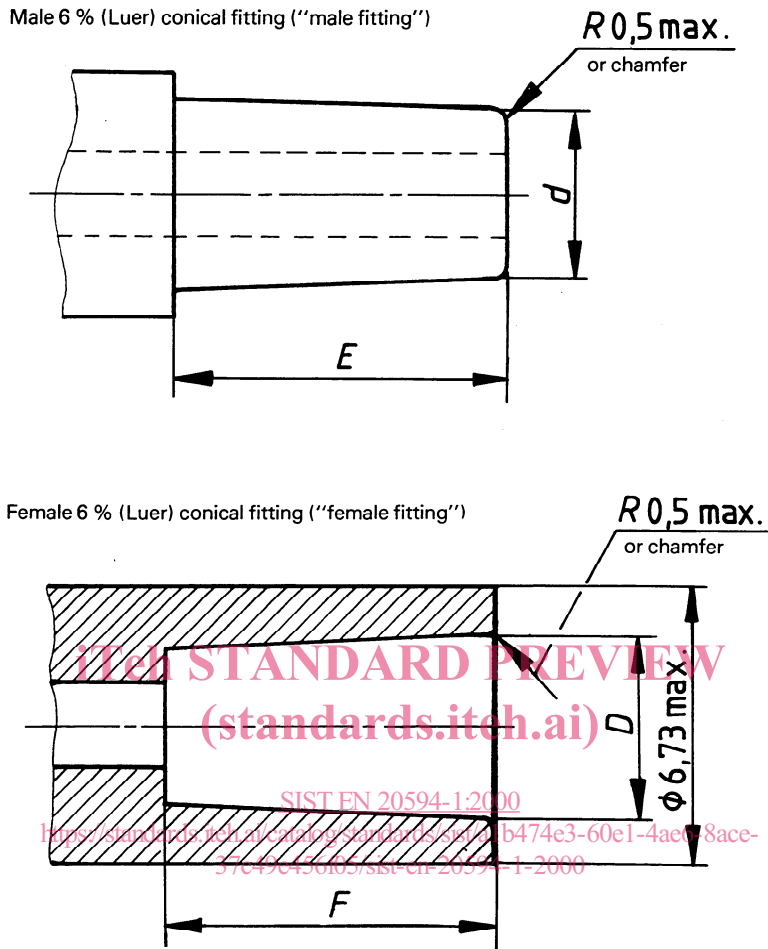


Figure 1 — Typical 6 % (Luer) conical fittings  
(see the corresponding values in the table)

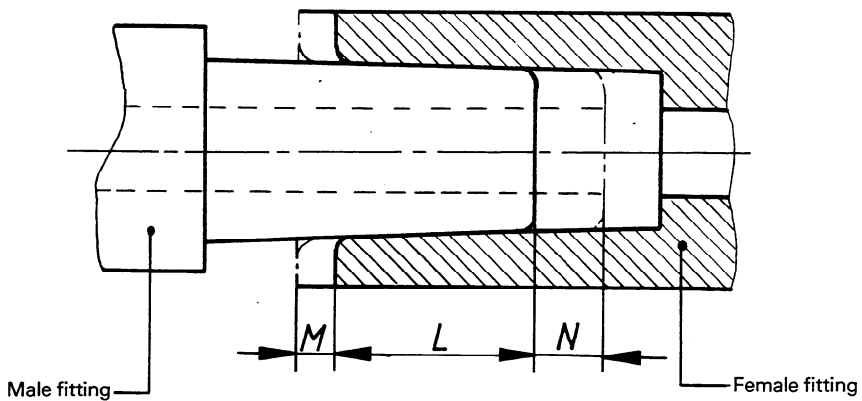


Figure 2 — Typical assembly of 6 % (Luer) conical fittings  
(see the corresponding values in the table)



Table — Dimensions of 6 % (Luer) conical fittings

Reference		Designation	Dimensions (mm)		
			rigid material	semi-rigid material	
Basic dimensions	$d$ {	min.	Minimum diameter of the end of the male conical fitting (reference diameter)	3,925	3,925
		max.	Maximum diameter at the end of the male conical fitting	3,990	4,027
	$D$ {	min.	Minimum diameter at the opening of the female conical fitting	4,270	4,270
		max.	Maximum diameter at the opening of the female conical fitting	4,315	4,315
		$E$	Minimum length of the male conical fitting	7,500	7,500
		$F$	Minimum depth of the female conical fitting	7,500	7,500
Other dimensions	$L^*$	Minimum length of engagement	4,665	4,050	
	$M^*$	Tolerance for length of engagement of the female conical fitting	0,750	0,750	
	$N^*$	Tolerance for length of engagement of the male conical fitting	1,083	1,700	
	$R^{**}$ max.	Radius of curvature	0,5	0,5	

\* Dimensions  $L$ ,  $M$  and  $N$  are derived from the basic dimensions.

\*\* Or equivalent entry chamfer without any sharp corners.

## 4 Requirements

The axis of the conical fitting under test shall be horizontal.

### 4.1 Gauging

When tested in accordance with 5.1, the conical fitting shall satisfy the requirements specified in 4.1.1 and 4.1.2.

4.1.1 The small end of the male conical fitting shall lie between the two limit planes of the gauge and the larger end of the tapered portion shall extend beyond the datum plane of the gauge.

Rocking shall not be evident between the gauge and the fitting made of rigid<sup>1)</sup> material undergoing test.

4.1.2 The plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge.

Rocking shall not be evident between the gauge and the fitting made of rigid<sup>1)</sup> material undergoing test.

### 4.2 Liquid leakage

There shall be no leakage sufficient to form a falling drop of water under the test conditions described in 5.2.

### 4.3 Air leakage

Continued formation of air bubbles shall not be evident under the test conditions described in 5.3. Bubbles formed during the first 5 s shall be ignored.

### 4.4 Separation force

The conical fitting under test shall remain attached to the test fixture, under the test conditions described in 5.4.

### 4.5 Stress cracking

There shall be no evidence of stress cracking of the conical fitting, under the test conditions described in 5.5.

NOTE — Materials used for conical fittings should be resistant to stress cracking in environments likely to be encountered in use (for example when in contact with alcohols).

1) The test for freedom from rocking may be found useful for evaluating semi-rigid fittings.