INTERNATIONAL STANDARD

Second edition 1998-09-01

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

Part 2: Lock fittings

iTeh STANDARD PREVIEW Assemblages coniques à 6 % (Luer) des seringues et aiguilles et de certains autres appareils à usage médical —

Partie 2: Assemblages à verrouillage ISO 594-2:1998 https://standards.iteh.ai/catalog/standards/sist/9c843099-ab5f-43c3-a25e-

e16337eecd3f/iso-594-2-1998



Contents

Page

1 Scope1	
2 Normative references	1
3 Dimensions and tolerances	1
4 Requirements	6
5 Test methods	6

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 594-2:1998 https://standards.iteh.ai/catalog/standards/sist/9c843099-ab5f-43c3-a25ee16337eecd3f/iso-594-2-1998

© ISO 1998

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization Case postale 56 • CH-1211 Genève 20 • Switzerland Internet iso@iso.ch Printed in Switzerland

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.

International Standard ISO 594-2 was prepared by Technical Committee ISO/TC 84, Medical devices for injections.

This second edition cancels and replaces the first edition (ISO 594-2:1991), of which it constitutes a minor revision. (standards.iteh.ai)

It corresponds to European Standard EN 1707:1996, prepared by Technical Committee CEN/TC 205, *Non-active medical devices*.

ISO 594 consists of the following parts, under the general title *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment*:

- Part 1: General specifications
- Part 2: Lock fittings

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 594-2:1998 https://standards.iteh.ai/catalog/standards/sist/9c843099-ab5f-43c3-a25ee16337eecd3f/iso-594-2-1998

Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings

1 Scope

This part of ISO 594 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 **ndards.iteh.ai**)

2 Normative references

ISO 594-2:1998

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 594. For dated references, subsequent amendments to or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 594 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 468, Surface roughness — Parameters, their values and general rules for specifying requirements.

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

ISO 7886-1, 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 ISO 594-1 apply to the relevant conical part of the fitting described in clause 4 of this part of ISO 594.

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.



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

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



NOTE For other dimensions, see Figure 1.





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, a maximum K





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

Table 1 — Dimensions of 6 % (Luer) rigid conical lock fittings

Dimensions in millimetres

Symbol	Designation	Dimensions	
		Figures 1, 2, 3a) and 4	Figures 3b) and 3c)
α	Angle of thread or lug bearing surface against separation with the plane perpendicular to the axis of lock fitting	$25^{\circ} \frac{+5^{\circ}}{0^{\circ}}$	$25^{\circ} {}^{+5^{\circ}}_{0^{\circ}}$
β	Minimum angle of internal thread non-bearing surface against separation with the plane perpendicular to the axis of lock fitting	25°	_
γ	Minimum angle of external thread or lug non-bearing surface against separation with the plane perpendicular to the axis of the lock fitting	0°	0°
E	Minimum length of male lock fitting	7,5	_
F	Nominal distance from the face of the fitting to the base of the lug	_	0,20
G	Maximum outside diameter of female lock fitting at base of lugs or maximum inside diameter of external thread. This diameter shall not be increased for a distance from the hub face of 5,5 mm	6,73	5,7
Н	Root diameter of the thread of male lock fitting DPREVIE	8,0 ± 0,1	_
J	Crest diameter of the thread of male lock fitting.iteh.ai)	7,0 ± 0,2	_
К	Maximum thread width of male lock fitting at root	1	_
Р	Minimum projection of nozzale trional autoral and and sist/9c843099-ab5f-43c.	3-a25e-2,1	_
Q	Minimum thread crest width of male lock fittings	0,3	_
S	Lug crest width or thread crest width of female lock fitting with lugs or external thread	0,3 min.	0,27 max.
Т	Maximum distance from tip of male lock fitting to the bottom of first complete thread form of the internal thread	3,2	_
V	Maximum 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	5,0
W	Minimum 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	
X	Distance from axis of female lock fitting to extremity of lug	_	_
2 <i>X</i>	Outside diameter across the lugs or external thread	7,83 0 _0,1	7,80 ⁰ _{-0,1}
Y	Maximum 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	1,30
Z	Width across the lugs at external thread		6,50 ⁰ _{-0,1}
Pitch	Nominal pitch of double-start, right-hand thread of female lock fitting - 5 mm lead	2,5	_