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Small-bore connectors for liquids and gases in healthcare applications —

Part 7:

Connectors with 6% (Luer) taper for intravascular or hypodermic applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 7: Raccords destinés à des applications intravasculaires ou hypodermiques

ICS 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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21	Contents	Page
22	Foreword	vi
23	Introduction	vi
24	1 Scope	1
25	2 Normative references	1
26	3 Terms and definitions	2
27	4 General requirements	3
28	4.1 General requirements for LUER CONNECTORS	3
29	4.2 Material used for LUER CONNECTORS	4
30	5 Dimensional requirements for LUER CONNECTORS	4
31	6 Performance requirements	4
32	6.1 General performance requirements	4
33	6.2 Fluid leakage	4
34	6.3 Subatmospheric-pressure air leakage	5
35	6.4 Stress cracking	5
36	6.5 Resistance to separation from axial load	5
37	6.6 Resistance to separation from unscrewing	5
38	6.7 Resistance to overriding	6
39	7 Design guidance	6
40	Annex A (informative) Rationale and guidance	7
41	Annex B (normative) LUER CONNECTORS	9
42	Annex C (normative) Reference CONNECTORS	19
43	Annex D (informative) Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within	
44	this APPLICATION	25
45	Annex E (informative) Summary of the usability requirements for SMALL-BORE CONNECTORS for	
46	intravascular or hypodermic APPLICATIONS	27
47	Annex F (informative) Summary of SMALL-BORE CONNECTOR criteria and requirements for	
48	intravascular or hypodermic APPLICATIONS	32
49	Annex G (informative) Summary of assessment of the design of the SMALL-BORE CONNECTOR for	
50	intravascular or hypodermic APPLICATIONS	35
51	Annex H (informative) Historical plug and ring test gauges	37
52	Annex I (informative) Reference to the Essential Principles	38
53	Bibliography	40
54	Terminology - Alphabetized index of defined terms	41
55	Annex ZA (informative) Relationship between this document and the Essential Requirements of	
56	EU Directive 93/42/EEC	42
57		
58	Figures	
59	Figure B.1 — Male LUER SLIP CONNECTOR (L1)	9
60	Figure B.2 — Female LUER SLIP CONNECTOR (L1)	10

61	Figure B.3 — Male LUER LOCK CONNECTOR (L2), with fixed collar	11
62	Figure B.4 — Male LUER LOCK CONNECTOR (L2), with floating or rotatable collar	11
63	Figure B.5 — Female LUER LOCK CONNECTOR (L2)	13
64	Figure B.6 — Female LUER LOCK CONNECTOR with lugs at right angle to axis (L2), variant A	15
65	Figure B.7 — Female LUER LOCK CONNECTOR with lugs at right angle to axis (L2), variant B	17
66	Figure B.8 — Female LUER LOCK CONNECTOR with lugs at right angle to axis (L2), variant C	18
67	Figure C.1 — Female reference LUER LOCK CONNECTOR for testing male LUER CONNECTORS for leakage,	
68	disconnection by unscrewing, separation from unscrewing, stress cracking and NON-	
69	INTERCONNECTABLE characteristics	20
70	Figure C.2 — Female reference LUER SLIP CONNECTOR for testing male LUER CONNECTORS for leakage,	
71	disconnection by unscrewing, separation from unscrewing, stress cracking and NON-	
72	INTERCONNECTABLE characteristics	21
73	Figure C.3 — Female reference CONNECTOR for testing male LUER LOCK CONNECTOR for separation from	
74	axial load and resistance to overriding	22
75	Figure C.4 — Male reference LUER LOCK CONNECTOR for testing female LUER CONNECTORS for leakage,	
76	disconnection by unscrewing, separation from unscrewing, stress cracking and NON-	
77	INTERCONNECTABLE characteristics	22
78	Figure C.5 — Male reference LUER SLIP CONNECTOR for testing female LUER CONNECTORS for leakage,	
79	disconnection by unscrewing, separation from unscrewing, stress cracking and NON-	
80	INTERCONNECTABLE characteristics	23
81	Figure C.6 — Male reference CONNECTOR for testing female LUER LOCK CONNECTOR for separation from	
82	axial load and resistance to overriding	23
83	Figure G.1 — Permissible sphygmomanometer to LUER SLIP CONNECTOR misconnection	36
84	Figure H.1 — Female ring gauge for male LUER CONNECTORS	37
85	Figure H.2 — Male plug gauge for FEMALE LUER CONNECTORS	37
86		
87	Tables	
88	Table B.1 — Male LUER SLIP CONNECTOR dimensions (L1)	9
89	Table B.2 — Female LUER SLIP CONNECTOR dimensions (L1)	10
90	Table B.3 — Male LUER LOCK SMALL-BORE CONNECTOR with fixed collar dimensions (L2)	12
91	Table B.4 — Male LUER LOCK SMALL-BORE CONNECTOR with floating or rotatable collar dimensions (L2)	12
92	Table B.5 — Female LUER LOCK SMALL-BORE CONNECTOR dimensions (L2)	14
93	Table B.6 — Female LUER LOCK SMALL-BORE CONNECTOR dimensions (L2), variant A	16
94	Table B.7 — Female LUER LOCK SMALL-BORE CONNECTOR dimensions (L2), variant B	17
95	Table B.8 — Female LUER LOCK SMALL-BORE CONNECTOR dimensions (L2) with external lugs	18

96	Table D.1 — Examples of MEDICAL DEVICES with CONNECTIONS within this APPLICATION	
97	and their attributes	26
98	Table E.1 — USER PROFILE.....	27
99	Table E.2 — Use scenarios	28
100	Table F.1 — ISO 80369-1 list of specific design criteria and requirements for intravascular or	
101	hypodermic APPLICATIONS	32
102	Table I.1 — Correspondence between this document and the essential principles.....	38
103	Table ZA.1 — Correspondence between this document and Directive 93/42/EEC	42
104	Table ZA.2 — Relevant Essential Health and Safety Requirements (EHSRs) from Directive 2006/42/EC	
105	on machinery that are addressed by this document	42
106		

107 **Foreword**

108 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies
109 (ISO member bodies). The work of preparing International Standards is normally carried out through ISO
110 technical committees. Each member body interested in a subject for which a technical committee has been
111 established has the right to be represented on that committee. International organizations, governmental and
112 non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the
113 International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

114 International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

115 The main task of technical committees is to prepare International Standards. Draft International Standards
116 adopted by the technical committees are circulated to the member bodies for voting. Publication as an
117 International Standard requires approval by at least 75 % of the member bodies casting a vote.

118 Attention is drawn to the possibility that some of the elements of this document may be the subject of patent
119 rights. ISO shall not be held responsible for identifying any or all such patent rights.

120 ISO/IEC 80369-7 was prepared by a Joint Working Group of Technical Committee ISO/TC 210, *Quality*
121 *management and corresponding general aspects for medical devices*, IEC/TC 62, *Electrical equipment*,
122 Subcommittee SC 62D, *Electrical equipment in medical practice* and CEN/CENELEC TC3/WG 2, *Small-bore*
123 *connectors*.

124 This first edition cancels and replaces the first edition ISO 594-1:1986 and the second edition of
125 ISO 594-2:1998, clauses, subclauses, tables, figures, and annexes of which have been consolidated and
126 technically revised.

127 ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases*
128 *in healthcare applications*:

129 — *Part 1: General requirements*

130 — *Part 2: Connectors for breathing systems and driving gases applications*

131 — *Part 3: Connectors for enteral applications*

132 — *Part 4: Connectors for urethral and urinary applications¹*

133 — *Part 5: Connectors for limb cuff inflation applications*

134 — *Part 6: Connectors for neuraxial applications*

135 — *Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications (this standard)*

136 — *Part 20: Common test methods*

137 In this standard, the following print types are used:

138 — Requirements and definitions: roman type.

¹ To be developed.

- 139 — Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative
140 text of tables is also in a smaller type.
- 141 — TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPITALS.
- 142 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of
143 the conditions is true.
- 144 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part
145 2. For the purposes of this standard, the auxiliary verb:
- 146 — “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- 147 — “should” means that compliance with a requirement or a test is recommended but is not mandatory for
148 compliance with this standard;
- 149 — “may” is used to describe a permissible way to achieve compliance with a requirement or test.
- 150 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that
151 there is guidance or rationale related to that item in Annex A.
- 152 The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers
153 and testing organizations may need a transitional period following publication of a new, amended or revised
154 ISO or IEC publication in which to make products in accordance with the new requirements and to equip
155 themselves for conducting new or revised tests. It is the recommendation of the committees that the content of
156 this publication be adopted for implementation nationally not earlier than 3 years from the date of publication
157 for equipment newly designed and not earlier than 5 years from the date of publication for equipment already
158 in production.

159 **Introduction**

160 The standards in this series were developed to prevent misconnection between SMALL-BORE CONNECTORS
161 used in different APPLICATIONS. Part 1 of the series documents the necessary measures and PROCEDURES to
162 prevent misconnection and defines the APPLICATIONS. Part 20 contains the common TEST METHODS to support
163 the functional requirements for SMALL-BORE CONNECTORS. The other parts specify the designs of SMALL-BORE
164 CONNECTORS for each APPLICATION.

165 This part of ISO 80369 includes the dimensions and drawings of CONNECTORS intended to be used as conical
166 fittings with a 6 % (Luer) taper for CONNECTIONS in intravascular or hypodermic APPLICATIONS of MEDICAL
167 DEVICES and ACCESSORIES. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used
168 in different APPLICATION categories.

169 Criteria and requirements in this standard were developed using the informative summary of USER PROFILES,
170 use scenarios, and use environments in Annex E as a guide.

171 This International Standard contains the following major technical revisions to the previous ISO 594-1 and
172 ISO 594-2 standards:

- 173 a) New terms and definitions have been added to this standard to more clearly define the various types of
174 LUER CONNECTORS included in the scope of this standard. This International Standard more broadly
175 describes the requirements for the CONNECTORS used for intravascular or hypodermic APPLICATIONS,
176 unlike the previous ISO 594-1 and ISO 594-2 standards that are replaced by this standard, which only
177 described the requirements for the fittings (intended CONNECTION surfaces) of these CONNECTORS. This
178 distinction is important to define here because the previous standards do not contain the terms
179 CONNECTOR or CONNECTION and the ISO 80369 family of standards does not use the term fitting.
- 180 b) Requirements for certain dimensions not previously identified in ISO 594-1 and ISO 594-2 are added to
181 this standard to reduce the RISK of misconnections between MEDICAL DEVICES or ACCESSORIES for different
182 APPLICATIONS with the SMALL-BORE CONNECTORS that are being developed under other parts of the
183 ISO 80369 series of standards. These new dimensions were selected to represent the current design and
184 dimensions of LUER CONNECTORS in clinical use at the time this standard was developed. The term "6 %
185 (Luer) taper" used throughout the previous standards has also been clarified to the more commonly used
186 equivalent angular dimension (in degrees).
- 187 c) Requirements for gauging of LUER CONNECTORS made from SEMI-RIGID MATERIALS using plug and ring test
188 gauges have been replaced by dimensional requirements, which are more precise and essential for
189 reducing the RISK of misconnection with the other CONNECTORS identified in ISO 80369-1. The historical
190 gauging TEST METHODS are retained in this standard for reference in informative Annex H.
- 191 d) Separate requirements for LUER CONNECTORS made from SEMI-RIGID MATERIALS and RIGID MATERIALS have
192 been eliminated and combined as one common set of dimensions and requirements. This consolidation of
193 requirements was made to further reduce the RISK of misconnection with other SMALL-BORE CONNECTORS.

194