



**SLOVENSKI STANDARD**  
**oSIST prEN ISO/IEC 80369-20:2013**  
**01-november-2013**

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**Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 20.  
del: Splošne preskusne metode (ISO/DIS 80369-20:2013)**

Small-bore connectors for liquids and gases in healthcare applications - Part 20:  
Common test methods (ISO/DIS 80369-20:2013)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in  
medizinischen Anwendungen - Teil 20: Allgemeine Prüfverfahren (ISO/DIS 80369-  
20:2013)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie  
20: Méthodes d'essai courantes (ISO/DIS 80369-20:2013)

**Ta slovenski standard je istoveten z: prEN ISO/IEC 80369-20**

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**ICS:**

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters
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# DRAFT INTERNATIONAL STANDARD

## ISO/IEC DIS 80369-20

ISO/TC 210

Secretariat: ANSI

Voting begins on:  
2013-08-15Voting terminates on:  
2014-01-15

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

#### Part 20: Common test methods

*Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —  
Partie 20: Méthodes d'essai courantes*

ICS: 11.040.25

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#### 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.

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.

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## ISO/DIS 80369-20

30 **Foreword**

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

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

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

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

43 *ISO 80369-20 was prepared jointly by Technical Committees ISO/TC 210, Quality management and*  
 44 *corresponding general aspects for medical devices, and IEC/SC62D, Electromedical equipment used in*  
 45 *medical practice. The draft was circulated for voting to the national bodies of both ISO and IEC.*

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

48 — *Part 1: General requirements*

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

50 — *Part 3: Connectors for enteral applications*

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

52 — *Part 6: Connectors for neuraxial applications*

53 — *Part 7: Connectors for intravascular or hyopdermic applications*

54 — *Part 20: Common test methods (this standard)*

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

56 — Requirements and definitions: roman type.

57 — Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative  
 58 text of tables is also in a smaller type.

59 — TERMS DEFINED IN ISO 80369-1 AND CLAUSE 3 OF THIS STANDARD: SMALL CAPITALS.

60 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of  
 61 the conditions is true.

62 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part  
 63 2. For the purposes of this standard, the auxiliary verb:

- 64 — “shall” means that compliance with a requirement or a test is mandatory for compliance with this  
65 standard;
- 66 — “should” means that compliance with a requirement or a test is recommended but is not mandatory for  
67 compliance with this standard;
- 68 — “may” is used to describe a permissible way to achieve compliance with a requirement or test.
- 69 An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title indicates that  
70 there is guidance or rationale related to that item in Annex A.
- 71 The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers  
72 and testing organizations may need a transitional period following publication of a new, amended or revised  
73 ISO or IEC publication in which to make products in accordance with the new requirements and to equip  
74 themselves for conducting new or revised tests. It is the recommendation of the committee that the content of  
75 this publication be adopted for implementation nationally not earlier than 3 years from the date of publication  
76 for equipment newly designed and not earlier than 5 years from the date of publication for equipment already  
77 in production.
- 78

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## 79 Introduction

80 This part of ISO 80369 includes common TEST METHODS for evaluating the functional performance of the  
81 SMALL-BORE CONNECTORS of this series.

82 Many of the attribute TEST METHODS in this standard are extracted from the previous standards for Luer  
83 CONNECTORS, ISO 594-1 and ISO 594-2. Modifications of the TEST METHODS were developed to permit testing  
84 using variable data.

85 The TEST METHODS of this standard were developed based on the resolution of the comments generated  
86 during the Committee Draft phase of the development of the ISO 80369 series. During the development of the  
87 ISO 80369 series, the committee recognized that many of the performance requirements for the individual  
88 CONNECTORS of the series were the same. This standard was developed to standardize the TEST METHODS of  
89 this series. It is recognized that some CONNECTORS use TEST METHODS that are not common to other  
90 CONNECTORS. In this case, TEST METHODS specific to the CONNECTOR can be found in the corresponding part of  
91 this series. It is also recognized that not all CONNECTORS can be evaluated using each TEST METHOD in this part.  
92 The TEST METHODS applicable to each CONNECTOR are specified in the respective part of the ISO 80369 series.

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94 **Small-bore connectors for liquids and gases in healthcare**  
95 **applications — Part 20: Common test methods**

96 **1 \* Scope**

97 This part of ISO 80369 specifies the TEST METHODS to support the functional requirements for SMALL-BORE  
98 CONNECTORS intended to be used for CONNECTIONS of MEDICAL DEVICES and related ACCESSORIES.

99 This part of ISO 80369 does not specify the functional requirements for the MEDICAL DEVICES or ACCESSORIES  
100 that use these CONNECTORS. Such requirements are given in particular International Standards for specific  
101 MEDICAL DEVICES or ACCESSORIES.

102 **2 Normative references**

103 The following referenced documents are indispensable for the application of this document. For dated  
104 references, only the edition cited applies. For undated references, the latest edition of the referenced  
105 document (including any amendments) applies.

106 ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General*  
107 *requirements*

108 **3 Terms and definitions**

109 For the purposes of this document, the terms and definitions specified in ISO 80369-1:2010 and  
110 ISO 14971:2007 and the following apply. For convenience, the sources of all defined terms used in this  
111 document are given in the index at the end of this document.

112 **3.1**

113 **TEST METHOD**

114 definitive PROCEDURE for evaluating CONNECTORS that produces a test result

115 **3.2**

116 **TYPE TEST**

117 test on a representative sample with the objective of determining if the CONNECTOR, as designed and  
118 manufactured, can meet the requirements of this standard

119 [SOURCE: IEC 60601-1:2005, definition 3.135 modified: deleted 'of the equipment' and replaced 'equipment'  
120 with 'CONNECTOR'.]

121 **4 TEST METHODS for SMALL-BORE CONNECTORS**

122 **4.1 Fluid leakage TEST METHOD by pressure decay**

123 Annex B contains the TYPE TEST for fluid leakage by pressure decay.

**ISO/DIS 80369-20**124 **4.2 Falling drop positive pressure liquid leakage TEST METHOD**

125 Annex C contains the TYPE TEST for liquid leakage.

126 **4.3 Subatmospheric-pressure air leakage TEST METHOD**

127 Annex D contains the TYPE TEST for subatmospheric-pressure air leakage.

128 **4.4 Stress cracking TEST METHOD**

129 Annex E contains the TYPE TEST for stress cracking.

130 **4.5 Resistance to separation from axial load TEST METHOD**

131 Annex F contains the TYPE TEST for resistance to separation from axial load.

132 **4.6 Resistance to separation from unscrewing TEST METHOD**

133 Annex G contains the TYPE TEST for resistance to separation from unscrewing.

134 **4.7 Resistance to overriding TEST METHOD**

135 Annex H contains the TYPE TEST for resistance to overriding.

136 **4.8 Disconnection by unscrewing TEST METHOD**

137 Annex I contains the TYPE TEST for disconnection by unscrewing.

138 **4.9 Variable data TEST METHODS**

139 Annex J contains the TYPE TEST modifications to the previous TEST METHODS utilizing variable test data.

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143  
144

## Annex A (informative)

### Rationale and Guidance

#### 145 **A.1 General guidance**

146 This Annex provides a rationale for some requirements of ISO 80369-20 and is intended for those who are  
147 familiar with the subject of ISO 80369-20 but who have not participated in its development. An understanding  
148 of the rationale underlying these requirements is considered to be essential for their proper application.  
149 Furthermore, as clinical practice and technology change, it is believed that a rationale for the present  
150 requirements will facilitate any revision of this document necessitated by those developments.

151 The committee attempted to harmonize the functional TEST METHODS for the CONNECTORS of each APPLICATION  
152 in this international standard. The TEST METHOD annexes in this standard describe a specific test PROCEDURE  
153 for a TYPE TEST but allow for modification to specific test conditions or acceptance criteria as necessary for  
154 each APPLICATION.

155 Many of the TEST METHODS in this standard were extracted from the ISO 594 series of standards. The  
156 committee attempted to minimize changes to these TEST METHODS. However, changes were made to TEST  
157 METHODS which contained subjective acceptance criteria.

158 The assembly PROCEDURE in each Annex mimics the assembly PROCEDURE that was extracted from ISO 594.  
159 An additional clarification was made for CONNECTORS with a floating or rotatable locking collar. Test sample  
160 preconditioning and environmental test condition requirements were added to each Annex.

#### 161 **A.2 Rationale for particular clauses and subclauses**

162 The clauses and subclauses in this Annex have been numbered to correspond to the numbering of the  
163 clauses and subclauses of this document to which they refer. The numbering is, therefore, not consecutive.

##### 164 **Clause 1 Scope**

165 The ease of assembly TEST METHOD that was part of the ISO 594 series has been removed as a requirement  
166 from the APPLICATION parts of this series of standards and is not present in this standard. The acceptance  
167 criterion of the ISO 594 series for ease of assembly was subjective. It was underdefined for a standardized  
168 TEST METHOD, i.e. "a satisfactory fit" is not repeatable. Furthermore, the intent of the ease of assembly test was  
169 to ensure that the USER can complete the CONNECTION using the mating halves of the CONNECTOR. This  
170 requirement is satisfied by the requirement for usability validation for all new connectors being added to this  
171 series of standards. Therefore, the ease of assembly TEST METHOD has been omitted from the ISO 80369  
172 series of standards.

173 **Subclause B.2.1 Test sample preconditioning**  
174 **Subclause C.2.1 Test sample preconditioning**  
175 **Subclause D.2.1 Test sample preconditioning**  
176 **Subclause E.2.1 Test sample preconditioning**  
177 **Subclause F.2.1 Test sample preconditioning**  
178 **Subclause G.2.1 Test sample preconditioning**  
179 **Subclause H.2.1 Test sample preconditioning**  
180 **Subclause I.2.1 Test sample preconditioning**

181 Temperature range specified for testing is greater than that specified in ISO 594-1 and ISO 594-2 to evaluate  
182 the performance of CONNECTORS exposed to heated solutions and outdoor conditions.

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183 Temperature and humidity preconditioning requirements have been added in TYPE TESTS for hygroscopic  
 184 materials. Hygroscopic materials are known to absorb moisture from surrounding gases and liquids, which can  
 185 alter physical characteristics, dimensions and performance of CONNECTORS.

186 **Annex B Fluid leakage TEST METHOD by pressure decay**

187 This pressure decay TEST METHOD is a new TEST METHOD that was not part of the former ISO 594 series.  
 188 However, it is based upon the informative liquid leakage TEST METHOD of ISO 594-1:1986, Annex A. The  
 189 acceptance criteria are the same.

190 **Annex C Falling drop positive pressure liquid leakage TEST METHOD**

191 This liquid leakage TEST METHOD is performed in the same manner as in the ISO 594 series. The pressure that  
 192 the test is performed at is modified from "300 to 330 kPa" to "at least 300 kPa unless otherwise specified."

193 **Annex D Subatmospheric-pressure air leakage TEST METHOD**

194 This subatmospheric-pressure air leakage TEST METHOD is a new TEST METHOD that was not part of the former  
 195 ISO 594 series. The ISO 594 series TEST METHOD for subatmospheric-pressure (5.3 of both part 1 and part 2)  
 196 creates an unspecified subatmospheric test pressure and asks the observer to look for continued formation of  
 197 bubbles of an unspecified size. The TEST METHOD included in this standard was developed during the  
 198 committee drafts of ISO 80369-2 and ISO 80369-6 and specifies the subatmospheric-pressure and leakage  
 199 rate. The leakage rate from ISO 594-1:1986, Annex A, for positive pressure liquid leakage was used for the  
 200 acceptance criteria for this TEST METHOD.

201 **Annex E Stress cracking TEST METHOD**

202 This stress cracking TEST METHOD is performed in the same manner as in the ISO 594 series. The acceptance  
 203 criteria have been changed to require passing a functional leak test after the stress cracking test has been  
 204 performed.

205 **Annex F Resistance to separation from axial load TEST METHOD**

206 This resistance to separation from axial load TEST METHOD is performed in the same manner as in the ISO 594  
 207 series. The title and principle have been elaborated to describe the intent of the test.

208 **Annex G Resistance to separation from unscrewing TEST METHOD**

209 This resistance to separation from unscrewing TEST METHOD is performed in the same manner as the ISO 594  
 210 series. The title and principle have been elaborated to describe the intent of the test.

211 **Annex H Resistance to overriding TEST METHOD**

212 This resistance to overriding TEST METHOD is performed in the same manner as the ISO 594 series.

213 **Annex I Disconnection by unscrewing TEST METHOD**

214 This disconnection by unscrewing TEST METHOD supplements the TEST METHOD described in the ISO 594  
 215 series. It is intended to ensure that CONNECTORS, which can be connected and disconnected multiple times  
 216 per day, can be successfully disconnected by the USER.

217 **Annex J Alternate TEST METHODS to generate variable data for statistical analysis**

218 Multiple TEST METHODS in this standard are written as attribute data TEST METHODS that can be modified to  
 219 become variable data TEST METHODS.

220 Attribute data tests are more commonly known as pass/fail tests. Attribute data tests can only determine if the  
 221 specification is met. They provide no indication of how the CONNECTOR fails and typically require a large  
 222 sample size to have the same statistical power as an equivalent variable data test.