



SLOVENSKI STANDARD
oSIST prEN ISO 80369-20:2023
01-junij-2023

Nadomešča:
SIST EN ISO/IEC 80369-20:2015

Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 20.
del: Splošne preskusne metode (ISO/DIS 80369-20:2023)

Small-bore connectors for liquids and gases in healthcare applications - Part 20:
Common test methods (ISO/DIS 80369-20:2023)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in
medizinischen Anwendungen - Teil 20: Allgemeine Prüfverfahren (ISO/DIS 80369-
20:2023)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie
20: Méthodes d'essai communes (ISO/DIS 80369-20:2023)

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

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters
-----------	--	-----------------------------------

oSIST prEN ISO 80369-20:2023 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 80369-20

ISO/TC 210

Secretariat: ANSI

Voting begins on:
2023-03-14Voting terminates on:
2023-06-06

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 communes*

ICS: 11.040.20; 11.040.10; 11.040.25

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN ISO 80369-20:2023](https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023)

<https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023>

This document is circulated as received from the committee secretariat.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

ISO/CEN PARALLEL PROCESSING



Reference number
ISO/DIS 80369-20:2023(E)

© ISO 2023

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 80369-20:2023](https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023)

<https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2023

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office

Case postale 56 • CH-1211 Geneva 20

Tel. + 41 22 749 01 11

Fax + 41 22 749 09 47

E-mail copyright@iso.org

Web www.iso.org

Published in Switzerland.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 80369-20:2023](https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023)

<https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023>

ISO/DIS 80369-20:2023(E)

1	Contents	Page
2	Foreword	5
3	Introduction	7
4	1 Scope	1
5	2 Normative references	1
6	3 Terms and definitions	1
7	4 Test methods for small-bore connectors	1
8	Annex A (informative) Rationale and guidance	3
9	Annex B (normative) Leakage by pressure decay test method	6
10	Annex C (normative) Falling drop positive-pressure liquid leakage test method	9
11	Annex D (normative) Subatmospheric-pressure air leakage test method	11
12	Annex E (normative) Stress cracking test method	14
13	Annex F (normative) Resistance to separation from axial load test method	16
14	Annex G (normative) Resistance to separation from unscrewing test method	18
15	Annex H (normative) Resistance to overriding test method	20
16	Annex I (normative) Disconnection by unscrewing test method	22
17	Annex J (informative) Modification of the test methods to generate variable data	
18	for statistical analysis	24
19	Annex K (normative) Air leakage during aspiration test method	27
20	Bibliography	30
21	Terminology — Alphabetized index of defined terms	31
22		

23 Foreword

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

31 The procedures used to develop this document and those intended for its further maintenance are
32 described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the
33 different types of ISO documents should be noted. This document was drafted in accordance with the
34 editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

35 Attention is drawn to the possibility that some of the elements of this document may be the subject of
36 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any
37 patent rights identified during the development of the document will be in the Introduction and/or on
38 the ISO list of patent declarations received (see www.iso.org/patents).

39 Any trade name used in this document is information given for the convenience of users and does not
40 constitute an endorsement.

41 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and
42 expressions related to conformity assessment, as well as information about ISO's adherence to the World
43 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see
44 www.iso.org/iso/foreword.html.

45 This document was prepared by Technical Committee ISO/TC 210, *Quality management and*
46 *corresponding general aspects for medical devices*, and IEC/SC62D, *Electromedical equipment* in
47 collaboration with the European Committee for Standardization (CEN/CLC) Technical Committee CEN/
48 CLC JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with
49 the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

50 This second edition cancels and replaces the first edition (ISO 80369-20:2015), which has been
51 technically revised. The main changes compared to the previous edition are as follows:

52 Major technical revision of the *test methods* described in annex B “Leakage by pressure decay test
53 method” and annex D “Subatmospheric-pressure air leakage test method.” As acceptance criterion the
54 leakage rate is replaced by the pressure change. Three defined mandatory test conditions were defined.
55 More information about this change is included in Annex A.

- 56 — Introduction of a new attributive *test method* “Air leakage during aspiration” as Annex K.
- 57 — Editorial revision of the assembling *procedures* of a *connector* under test. All annexes with *test*
58 *methods* are affected.
- 59 — Editorial update due to the latest ISO formatting standards.
- 60 — Replacing the terms “male” by “cone” and “female” by “socket” in the description of a *connector* half.
- 61 — Update of dated normative references.
- 62 — Technical revision of the *test methods* described in Annex B and Annex D. All test conditions have
63 been specified thereby the leakage rate calculation has become superfluous.
- 64 — Definition for *type test* is updated.
- 65 — The range of environmental test conditions for relative humidity has been expanded.
- 66 — The requirements for test reports have been extended.

ISO/DIS 80369-20:2023(E)

67 — Clarified that all tests are intended be *type tests*.

68 A list of all parts in the ISO and IEC 80369 series can be found on the ISO and IEC websites.

69 Any feedback or questions on this document should be directed to the user's national standards
70 body. A complete listing of these bodies can be found at www.iso.org/members.html and
71 www.iec.ch/national-committees.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

oSIST prEN ISO 80369-20:2023

<https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023>

72 Introduction

73 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
74 of the conditions is true.

75 In this document, the following verbal forms are used:

- 76 — “shall” indicates a requirement;
- 77 — “should” indicates a recommendation;
- 78 — “may” indicates a permission;
- 79 — “can” is used to describe a possibility or capability.

80 This document describes the common *test methods* for evaluating the performance requirements of the
81 *small-bore connectors* specified in this series.

82 It is recognized that not all *connectors* can be evaluated using each *test method* in this document. The *test*
83 *methods* applicable to each *connector* are specified in the respective part of the ISO and IEC 80369 series.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN ISO 80369-20:2023](https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023)

<https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023>

84 **Small-bore connectors for liquids and gases in healthcare** 85 **applications — Part 20: Common test methods**

86 **1 Scope**

87 NOTE 1 There is guidance or rationale for this Clause contained in Clause A.2.

88 This document specifies the common *test methods* to evaluate the performance requirements for *small-*
89 *bore connectors* specified in the ISO and IEC 80369 series.

90 NOTE 2 The *application* parts of the ISO and IEC 80369 series specify which tests are required as well as their
91 acceptance criterion.

92 **2 Normative references**

93 The following documents are referred to in the text in such a way that some or all of their content
94 constitutes requirements of this document. For dated references, only the edition cited applies. For
95 undated references, the latest edition of the referenced document (including any amendments) applies.

96 NOTE Informative references are listed in the bibliography.

97 ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

98 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1:*
99 *General requirements*

100 **3 Terms and definitions**

101 For the purposes of this document, the terms and definitions given in ISO 80369-1:2018, ISO 14971:2019,
102 and the following apply.

103 ISO and IEC maintain terminological databases for use in standardization at the following addresses:

104 — ISO Online browsing platform: available at <https://www.iso.org/obp>

105 — IEC Electropedia: available at <http://www.electropedia.org/>

106 NOTE An alphabetized index of defined terms is found following the bibliography.

107 **3.1**

108 **type test**

109 test on a representative sample of the equipment with the objective of determining if the equipment, as
110 designed and manufactured, can meet the requirements of this document

111 [SOURCE: IEC 60601-1:2005, 3.135, modified — replaced “standard” with “document.”]

112 **4 Test methods for small-bore connectors**

113 Table 1 contains the list of *test methods* and their corresponding Annex included in this document.
114 *Manufacturers* may use the modified *test methods* of Annex J. The tests to evaluate the performance
115 requirements for *small-bore connectors* specified in the ISO and IEC 80369 series described in this
116 document are intended be performed as *type tests*.

ISO/DIS 80369-20:2023(E)

117 NOTE The *application* parts of the ISO and IEC 80369 series specify which tests given in Table 1 are required as
 118 well as their acceptance criterion.

119

Table 1 — Test methods and corresponding Annex of this document

<i>Test method</i>	Annex of this document
Leakage by pressure decay	Annex B
Falling drop positive pressure liquid leakage	Annex C
Subatmospheric-pressure air leakage	Annex D
Stress cracking	Annex E
Resistance to separation from axial load	Annex F
Resistance to separation from unscrewing	Annex G
Resistance to overriding	Annex H
Disconnection by unscrewing	Annex I
Modification of the <i>test methods</i> to generate variable data for statistical analysis	Annex J
Air leakage during aspiration	Annex K

iTeh STANDARD PREVIEW
 (standards.iteh.ai)

[oSIST prEN ISO 80369-20:2023](https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023)

<https://standards.iteh.ai/catalog/standards/sist/dac831fd-7c16-4416-a412-6211d75322be/osist-pren-iso-80369-20-2023>

120
121
122

Annex A (informative) Rationale and guidance

123 A.1 General guidance

124 This Annex provides a rationale for some requirements of this document and is intended for those who
125 are familiar with the subject of this document, but who have not participated in its development. An
126 understanding of the rationales underlying these requirements is considered to be essential for their
127 proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale
128 for the present requirements will facilitate any revision of this document necessitated by those
129 developments.

130 The committee attempted to harmonize the functional *test methods* for the *connectors* of each *application*
131 in this document. The *test method* Annexes in this document describe a specific *test procedure* for a *type*
132 *test* but allow for modification to specific test conditions or acceptance criteria as necessary for each
133 *application*.

134 Many of the *test methods* in this document were extracted from the ISO 594 series of documents (now
135 withdrawn). The committee attempted to minimize changes to these *test methods*. However, changes
136 were made to *test methods* which contained subjective acceptance criteria.

137 The assembly *procedure* in each Annex mimics the assembly *procedure* that was extracted from ISO 594.
138 An additional clarification was made for *connectors* with a floating or rotatable locking collar. Test sample
139 preconditioning and environmental test condition requirements were added to each Annex.

140 A.2 Rationale for particular clauses and subclauses

141 The numbering of the following rationales corresponds to the numbering of the clauses and subclauses
142 of this document. The numbering is, therefore, not consecutive.

143 — Clause 1 Scope

144 The ease of assembly *test method* that was part of the ISO 594 series has been removed as a
145 requirement from the *application* parts of the ISO and IEC 80369 series and is not present in this
146 document. The acceptance criterion of the ISO 594 series for ease of assembly was subjective. It was
147 underdefined for a standardized *test method*, i.e. “a satisfactory fit” is not repeatable. Furthermore,
148 the intent of the ease of assembly test was to ensure that the *user* can complete the *connection* using
149 the mating halves of the *connector*. This requirement is satisfied by the requirement for usability
150 validation for all new *connectors* being added to the ISO and IEC 80369 series. Therefore, the ease of
151 assembly *test method* has been omitted from the ISO and IEC 80369 series.

152 — Clause B.2, C.2, D.2, E.2, F.2, G.2, H.2, I.2, K.2 Test conditions

153 Clause 2 in each *test method* includes preconditioning and environmental test requirements.

154 Temperature and humidity preconditioning requirements from ISO 594-1 and ISO 594-2 also have
155 been added in the *test methods* for hygroscopic materials, as these materials are known to absorb
156 moisture from surrounding gases and liquids, which can alter physical characteristics, dimensions,
157 and performance of *connectors*. The impact of humidity and temperature for materials can be
158 evaluated using manufacturing data, material technical data or comparative study.

159 The temperature range specified for testing is identical to that specified in ISO 594-1 and ISO 594-2.
160 However, it is permitted to utilize different ranges if specified in the relevant *application* part of these
161 series of the ISO and IEC 80369 series, to evaluate the performance of *connectors* exposed to heated
162 solutions and outdoor conditions.