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

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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**

ICS:

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

oSIST prEN ISO/IEC 80369-20:2013 **en**

DRAFT INTERNATIONAL STANDARD

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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

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.

Reference number
ISO/IEC DIS 80369-20:2013(E)

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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 2.

The main task of technical committees is to prepare International Standards. 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.

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

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

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

— *Part 1: General requirements*

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

— *Part 3: Connectors for enteral applications*

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

— *Part 6: Connectors for neuraxial applications*

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

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

In this standard, the following print types are used:

— Requirements and definitions: roman type.

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

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

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

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 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

Introduction

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

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

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

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

1 * Scope

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

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

2 Normative references

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

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

3 Terms and definitions

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

3.1
TEST METHOD
definitive PROCEDURE for evaluating CONNECTORS that produces a test result

3.2
TYPE TEST
test on a representative sample with the objective of determining if the CONNECTOR, as designed and manufactured, can meet the requirements of this standard

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

4 TEST METHODS for SMALL-BORE CONNECTORS

4.1 Fluid leakage TEST METHOD by pressure decay

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

4.2 Falling drop positive pressure liquid leakage TEST METHOD

Annex C contains the TYPE TEST for liquid leakage.

4.3 Subatmospheric-pressure air leakage TEST METHOD

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

4.4 Stress cracking TEST METHOD

Annex E contains the TYPE TEST for stress cracking.

4.5 Resistance to separation from axial load TEST METHOD

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

4.6 Resistance to separation from unscrewing TEST METHOD

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

4.7 Resistance to overriding TEST METHOD

Annex H contains the TYPE TEST for resistance to overriding.

4.8 Disconnection by unscrewing TEST METHOD

Annex I contains the TYPE TEST for disconnection by unscrewing.

4.9 Variable data TEST METHODS

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

Annex A
(informative)

Rationale and Guidance

A.1 General guidance

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

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

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

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

A.2 Rationale for particular clauses and subclauses

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

Clause 1 Scope

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

Subclause B.2.1 Test sample preconditioning
Subclause C.2.1 Test sample preconditioning
Subclause D.2.1 Test sample preconditioning
Subclause E.2.1 Test sample preconditioning
Subclause F.2.1 Test sample preconditioning
Subclause G.2.1 Test sample preconditioning
Subclause H.2.1 Test sample preconditioning
Subclause I.2.1 Test sample preconditioning

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

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

Annex B Fluid leakage TEST METHOD by pressure decay

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

Annex C Falling drop positive pressure liquid leakage TEST METHOD

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

Annex D Subatmospheric-pressure air leakage TEST METHOD

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

Annex E Stress cracking TEST METHOD

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

Annex F Resistance to separation from axial load TEST METHOD

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

Annex G Resistance to separation from unscrewing TEST METHOD

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

Annex H Resistance to overriding TEST METHOD

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

Annex I Disconnection by unscrewing TEST METHOD

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

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

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

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