SLOVENSKI STANDARD
kSIST FprEN ISO 80369-1:2015

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Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 1. del: Splošne zahteve (ISO/DIS 80369-1:2015)

Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO/DIS 80369-1:2015)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO/DIS 80369-1:2015)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 1: Exigences générales (ISO/DIS 80369-1:2015)

Ta slovenski standard je istoveten z: **FprEN ISO 80369-1 rev**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

kSIST FprEN ISO 80369-1:2015 **en**

DRAFT INTERNATIONAL STANDARD ISO/DIS 80369-1

ISO/TC **210** Secretariat: **ANSI**

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

Part 1:
General requirements

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

Partie 1: Exigences générales

(Revision of first edition [ISO 80369-1:2010])

ICS 11.040.10; 11.040.20

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

ISO/CEN PARALLEL PROCESSING

This final 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. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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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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 80369-1 was prepared by a Joint Working Group of Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, IEC/TC 62, *Electrical equipment*, Subcommittee SC D, *Electrical equipment in medical practice* and CEN/CENELEC TC 3/WG 2, *Small-bore connectors*.

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

— *Part 1: General requirements*

The following parts are under preparation:

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

— *Part 3: Connectors for enteral applications*

— *Part 4: Connectors for urethral and urinary applications*[1]

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

— *Part 6: Connectors for neuraxial applications*

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

— *Part 20: Common* TEST METHODS

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.

[1] Planned but not yet begun

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

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:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

In the 1990s concern grew regarding the proliferation of MEDICAL DEVICES fitted with Luer CONNECTORS and the reports of PATIENT death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases.

Concerns regarding the use of Luer CONNECTORS with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997 the newly created CHeF steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report CR 13825, in which they concluded that there is a problem arising from the use of a single CONNECTOR design to a number of incompatible APPLICATIONS. In a coronary care unit there are as many as 40 Luer CONNECTORS on the MEDICAL DEVICES used with a single PATIENT. Therefore it is not surprising that misconnections are made.

MEDICAL DEVICES have for many years followed the established principle of “safety under single fault conditions”. Simply stated this means that a single fault should not result in an unacceptable RISK. This principle is embodied in the requirements of numerous MEDICAL DEVICE standards. Extending this principle to the application of Luer CONNECTORS, i.e. that misconnection should not result in an unacceptable RISK to a PATIENT, the FTG recommended that the Luer CONNECTOR should be restricted to MEDICAL DEVICES intended to be connected to the vascular system or a hypodermic syringe. In addition, new designs of SMALL-BORE CONNECTORS should be developed for other APPLICATIONS, and these should be NON-INTERCONNECTABLE with Luer CONNECTORS and each other.

ISO/TR 16142:2006 addresses this type of problem in Essential Principle A.1.2:

> The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking into account the generally acknowledged state of the art.
>
> In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order:
>
> — identify hazards and the associated risks arising from the intended use and foreseeable misuse;
>
> — eliminate or reduce risks as far as possible (inherently safe design and construction);

It is understood that SMALL-BORE CONNECTOR systems cannot be designed to overcome all chances of misconnection or to eliminate deliberate misuse. However, a number of steps that would improve the current situation and lead to greater PATIENT safety can be taken. This will only be achieved through a long-term commitment involving industry, healthcare professionals, MEDICAL DEVICE purchasers and MEDICAL DEVICE regulatory authorities.

This is the second edition of ISO 80369-1 and it cancels and replaces ISO 80369-1:2010 which has been technically revised.

This series of standards has, wherever possible, restricted the number of CONNECTORS for each APPLICATION to one, unless there is sufficient clinical or technical evidence to have more.

It is expected that particular MEDICAL DEVICE standards will reference the interface requirements from the appropriate parts of the 80369 series.

131 This Part 1 of the 80369 series specifies the general requirements and TEST METHODS for assessing the NON-
132 INTERCONNECTABLE characteristics of SMALL-BORE CONNECTORS within the 80369 series. Parts 2 to 7 of the
133 80369 series specify the dimensional requirements for the interface CONNECTIONS and the basic performance
134 requirements for assessing the interconnectability of the connector mating halves.

135 Part 20 of the 80369 series specifies the TEST METHODS for assessing the basic performance requirements
136 specified in parts 2 to 7.

137 The designs and dimensions of SMALL-BORE CONNECTORS specified in Parts 2 to 7 of the 80369 series of
138 standards have been successfully assessed according to the requirements in this Part 1, i.e. have been
139 proven to be acceptable with regard to the RISK of misconnection.

140 This Part 1 of this International Standard contains general requirements to ensure the prevention of
141 misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. Subsequent parts of this
142 series of standards are expected to include requirements with regard to the CONNECTORS used in different
143 APPLICATION categories.

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Small-bore connectors for liquids and gases in healthcare applications —Part 1: General requirements

1 Scope

This part of ISO 80369 specifies general requirements for SMALL-BORE CONNECTORS, which convey liquids or gases in healthcare APPLICATIONS. These SMALL-BORE CONNECTORS are used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT.

This International Standard also specifies the healthcare fields in which these SMALL-BORE CONNECTORS are intended to be used.

These healthcare fields of use include, but are not limited to, APPLICATIONS for:

— BREATHING SYSTEMS and driving gases,

— enteral,

— urethral and urinary,

— limb cuff inflation,

— neuraxial devices, and

— intravascular or hypodermic.

This International Standard provides the methodology to assess NON-INTERCONNECTABLE characteristics of SMALL-BORE CONNECTORS based on their inherent design and dimensions in order to reduce the RISK of misconnections between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS and to reduce the RISK of misconnections between MEDICAL DEVICES with 6 % Luer CONNECTORS, and all other non-Luer CONNECTORS that will be developed under future parts of this series of standards.

This standard does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these SMALL-BORE CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 1 Subclause 5.8 allows for additional designs of SMALL-BORE CONNECTORS for inclusion in this series of standards for APPLICATIONS other than those already specified.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this series of standards into MEDICAL DEVICES, medical systems or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS as specified in the series of standards will be included.

NOTE 3 MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this series of standards to the Secretariat of ISO/TC 210 so that this feedback can be considered during the revision of the relevant part of this series of standards.

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 14971:2007, *Medical devices — Application of risk management to medical devices*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

ASTM D747-10, *Standard TEST METHOD for apparent bending modulus of plastics by means of a cantilever beam*

ASTM D790-10, *Standard TEST METHODs for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 14971:2007, IEC 62366:2007 and the following apply. For convenience, the sources of all defined terms used in this document are given in an index at the end of this standard.

3.1
ACCESSORY
additional part(s) for use with MEDICAL DEVICE in order to:

— achieve the INTENDED USE,

— adapt it to some special use,

— facilitate its use,

— enhance its performance, or

— enable its functions to be integrated with those of other MEDICAL DEVICES

[SOURCE: IEC 60601-1:2005, definition 3.3, modified — replaced 'equipment' with 'MEDICAL DEVICE'.]

3.2
APPLICATION
specific healthcare field in which a SMALL-BORE CONNECTOR is intended to be used

NOTE Annex E lists APPLICATIONS of SMALL-BORE CONNECTORS.

3.3
BREATHING SYSTEM
inspiratory and expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the PATIENT CONNECTION port and the exhaust port

3.4
CONNECTION
union or joining of mating halves of a CONNECTOR

3.5
CONNECTOR
mechanical device, consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

3.6
NON-INTERCONNECTABLE
having characteristics which incorporate geometries or other characteristics that prevent different CONNECTORS from making a CONNECTION

3.7
PATIENT
person undergoing a medical, surgical or dental PROCEDURE

[SOURCE: IEC 60601-1:2005+A1:2012, definition 3.76, modified — replaced 'living being (person or animal)' with 'person'.]

3.8
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL DEVICE

NOTE to entry: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, USER and RESPONSIBLE ORGANIZATION can be one and the same person.

[SOURCE: IEC 60601-1:2005, definition 3.101, modified — replaced 'an ME EQUIPMENT or an ME SYSTEM' with 'MEDICAL DEVICE'.]

3.9
SMALL-BORE
inner-fluid pathway of a CONNECTION with a diameter less than 8,5 mm

3.10
TEST METHOD
definitive PROCEDURE for evaluating CONNECTORS that produces a test result

3.11
TYPE TEST
test on a representative sample

Note to entry: More than one set of representative samples can be required, e.g. testing the SMALL-BORE CONNECTORS produced in each cavity of a multi-cavity mould.

4 *Materials

SMALL-BORE CONNECTORS specified in this series of standards shall be made of validated using a materials with a modulus of elasticity either in flexure or in tension greater than 700 MPa. Check compliance by application of the tests of ASTM D747 or ASTM D790 at (23 ± 2) °C and (50 ± 5) % relative humidity.

NOTE: Materials with a modulus of elasticity either in flexure or in tension less than 700 MPa may be used on the surfaces of the inner fluid pathways to enhance the performance of a CONNECTION in its clinical application.

5 Clinical APPLICATIONS

5.1 Incompatibility

SMALL-BORE CONNECTORS of each APPLICATION category specified in this International Standard shall be NON-INTERCONNECTABLE with any of the SMALL-BORE CONNECTORS of every other APPLICATION category for RISKS to be acceptable, unless otherwise indicated in this standard or within this series of standards.

Check compliance by confirming that OBJECTIVE EVIDENCE verifies that RISKS have been reduced to acceptable levels for the acceptability criteria specified in Annex B and other acceptability criteria established by the MANUFACTURER for NON-INTERCONNECTABLE characteristics. Verify that the SMALL-BORE CONNECTOR is NON-INTERCONNECTABLE.

NOTE 1: For the purpose of this standard, dimensional compliance with the various APPLICATION parts of this series of standards, is considered sufficient OBJECTIVE EVIDENCE of NON-INTERCONNECTABLE CHARACTERISTICS.

NOTE 2: Annex E lists examples of the sort of devices that the SMALL-BORE CONNECTORS within each APPLICATION can be used on.

