



BSI Standards Publication

Small-bore connectors for liquids and gases in healthcare applications

Part 3: Connectors for enteral applications

National foreword

This British Standard is the UK implementation of EN ISO 80369-3:2016+A1:2022. It is identical to ISO 80369-3:2016, incorporating amendment 1:2019. It supersedes BS EN ISO 80369-3:2016, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/210/5, Small Bore Connectors for Medical Devices.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English version

Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications (ISO 80369-3:2016)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 3: Raccords destinés à des applications entérales (ISO 80369-3:2016)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 3: Verbindungsstücke für enterale Anwendungen (ISO 80369-3:2016)

This European Standard was approved by CEN on 25 May 2016.

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Avenue Marnix 17, B-1000 Brussels**

European foreword

This document (EN ISO 80369-3:2016) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with Technical Committee CEN-CENELEC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 80369-3:2016 has been approved by CEN as EN ISO 80369-3:2016 without any modification.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA”, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes Z.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 5356-1:2004	EN ISO 5356-1:2004	ISO 5356-1:2004
ISO 5356-1:2015	EN ISO 5356-1:2015	ISO 5356-1:2015
ISO 5356-2:2006	EN ISO 5356-2:2007	ISO 5356-2:2006
ISO 5356-2:2012	EN ISO 5356-2:2012	ISO 5356-2:2012
ISO 8185:2007	EN ISO 8185:2009	ISO 8185:2007
EN 13544-2:2002	EN 13544-2:2002	—
EN 13544-2:2002+A1:2009	EN 13544-2:2002+A1:2009	—
ISO 80369-1:2010	EN ISO 80369-1:2010	ISO 80369-1:2010
ISO 80369-6:2016	EN ISO 80369-6:2016	ISO 80369-6:2016
ISO 80369-7:— ^a	EN ISO 80369-7:— ^a	ISO 80369-7:— ^a
ISO 80369-20:2015	EN ISO 80369-20:2015	ISO 80369-20:2015
ASTM D638-10	—	—
ASTM D790-10	—	—
^a To be published.		

European foreword to Amendment 1

The text of ISO 80369-3:2016/Amd 1:2019 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80369-3:2016/A1:2022 by Technical Committee CEN-CENELEC/ JTC 3 "Quality management and corresponding general aspects for medical devices" the secretariat of which is held by NEN.

This Amendment to the European Standard EN ISO 80369-3:2016 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

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

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN and CENELEC websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice to Amendment 1

The text of ISO 80369-3:2016/Amd 1:2019 has been approved by CEN-CENELEC as EN ISO 80369-3:2016/A1:2022 without any modification.

Annex ZA (informative)

Relationship between this document and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC / Directive 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced “as far as possible”, “to a minimum”, “to the lowest possible level”, “minimized” or “removed”, according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer’s policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 3 This Annex ZA is based on Normative References according to Table of References, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this document and Directive 93/42/EEC

Clause(s)/subclause(s) of this Document	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.1	7.5	
4.1, 5, 6.3, 6.4, 6.5, 6.6	9.1	
6.2	12.7.4	
4.1, 5, 6.3, 6.4, 6.5, 6.6	12.8.1	This Essential Requirement is partially covered in that by ensuring that the CONNECTOR does not leak and can only be connected to intended MEDICAL DEVICES or ACCESSORIES it permits a MEDICAL DEVICE to be capable of controlling the flowrate.

WARNING — Other requirements and other EU Directives may be applicable to the products falling within the scope of this document.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this Document. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Health and Safety Requirements (EHSRs) from Directive 2006/42/EC on machinery that are addressed by this document

Clause(s)/subclause(s) of this Document	EHSR of 2006/42/EC	Qualifying remarks/Notes
Clause 4, Clause 5, Clause 6	1.5.4	

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Contents

Page

Foreword	iv
Introduction	v
1 * Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	3
4.1 General requirements for the ENTERAL APPLICATION.....	3
4.2 Material used for ENTERAL SMALL-BORE CONNECTORS.....	3
4.3 TYPE TESTS.....	4
5 Dimensional requirements for ENTERAL SMALL-BORE CONNECTORS	4
6 Performance requirements	4
6.1 Fluid leakage.....	4
6.1.1 Fluid leakage requirement.....	4
6.1.2 Leakage by pressure decay.....	4
6.1.3 Positive pressure liquid leakage.....	4
6.2 Stress cracking.....	4
6.3 Resistance to separation from axial load.....	4
6.4 Resistance to separation from unscrewing.....	5
6.5 Resistance to overriding.....	5
6.6 Disconnection by unscrewing.....	5
Annex A (informative) Rationale and guidance	6
Annex B (normative) ENTERAL SMALL-BORE CONNECTORS	10
Annex C (normative) Reference CONNECTORS	16
Annex D (informative) Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION	21
Annex E (informative) Summary of the usability requirements for SMALL-BORE CONNECTORS for ENTERAL applications	22
Annex F (informative) Summary of SMALL-BORE CONNECTOR criteria and requirements for ENTERAL APPLICATIONS	27
Annex G (informative) Summary of assessment of the design of the CONNECTORS for ENTERAL APPLICATIONS	30
Annex H (informative) Reference to the essential principles	36
Annex I (informative) Terminology — Alphabetized index of defined terms	38
Bibliography	39

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.

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

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

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*
- *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 with 6 % (Luer) taper for intravascular or hypodermic applications*
- *Part 20: Common test methods*

An additional part on connectors for urethral and urinary applications is planned.

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from ENTERAL solutions being administered via incorrect routes, including intravenously and into the airway. Many incidents were reported leading to international recognition of the importance of these issues, and a need was identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver feed via the ENTERAL route.

The ISO 80369 series has been developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs of SMALL-BORE CONNECTORS to ensure that

- a) they do not misconnect with other SMALL-BORE CONNECTORS, and
- b) they safely and securely connect with their mating half.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design, the dimensions, and the drawings of SMALL-BORE CONNECTORS intended to be used in ENTERAL APPLICATIONS. [Annex D](#) to [Annex G](#) describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this part of ISO 80369 are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369 series for SMALL-BORE CONNECTORS, except as indicated in [G.2](#). If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS are to reduce the RISK of medication and liquid nutritional formula intended for ENTERAL administration from being delivered via an alternative route, such as intravenously or via an airway device.

During the development of this International Standard, the committee decided to cover the whole ENTERAL system but to have a separate International Standard for reservoir CONNECTORS. ISO 18250-3 specifies the requirements for ENTERAL reservoir CONNECTORS. This part of ISO 80369 includes the interface dimensions for SMALL-BORE CONNECTORS for access ports and PATIENT interfaces on ENTERAL feeding sets and ENTERAL syringes.

In this part of ISO 80369, 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 [Clause 3](#) or as noted: small capitals.

In this part of ISO 80369, 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 International Standard conform to usage described in ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80369,
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80369, and
- “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](#).

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

Part 3: Connectors for enteral applications

1 * Scope

This part of ISO 80369 specifies the dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS ON ENTERAL MEDICAL DEVICES and ACCESSORIES.

NOTE 1 ENTERAL MEDICAL DEVICES include ENTERAL feeding sets, ENTERAL drainage sets, ENTERAL syringes, and PATIENT interface devices including access ports.

This part of ISO 80369 does not specify the dimensions and 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.

This part of ISO 80369 does not specify requirements for SMALL-BORE CONNECTORS that are used for the following:

- gastric suction-only MEDICAL DEVICES;
- oral-only MEDICAL DEVICES;

EXAMPLE An oral tip syringe that is not intended to connect to another MEDICAL DEVICE. It is intended to administer directly to the PATIENT'S mouth.

- pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive ENTERAL MEDICAL DEVICES in place;
- A1 Text deleted. A1
- gastrointestinal endoscopy equipment;
- skin level gastrostomy MEDICAL DEVICES.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into ENTERAL MEDICAL DEVICES 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 ISO 80369, will be included.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

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

ISO 80369-6:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

ISO 80369-7:—¹⁾, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-10, *Standard test method for tensile properties of plastics*

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 given in ISO 80369-1, ISO 80369-7, ISO 80369-20, and ISO 14971 and the following apply.

NOTE For convenience, the sources of all defined terms used in this part of ISO 80369 are given in [Annex I](#).

3.1

ENTERAL

pertaining to the gastrointestinal tract

3.2

NORMAL USE

operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well

[SOURCE: IEC 60601-1:2005+A1:2012, 3.71, modified—replaced “OPERATOR” with “USER”.]

3.3

RATED

<value> term referring to a value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005, 3.97]

3.4

USER

person interacting with (i.e. operating or handling) the MEDICAL DEVICE

Note 1 to entry: This includes, but is not limited to, cleaners, maintainers and installers

Note 2 to entry: PATIENTS or other laypersons can be USERS

[SOURCE: IEC 62366-1:2015, 3.24]

3.5

USER PROFILE

summary of the mental, physical, and demographic traits of an intended USER population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

[SOURCE: IEC 62366-1:2015, 3.29]

1) To be published.

4 General requirements

4.1 General requirements for the ENTERAL APPLICATION

SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES intended for use in ENTERAL APPLICATIONS made in compliance with this part of ISO 80369 comply with ISO 80369-1 unless otherwise indicated in this part of ISO 80369.

The sealing surface of female E1 CONNECTOR may contact the thread surfaces of the N₂ female CONNECTOR, as specified in ISO 80369-6 in LMC conditions when evaluating the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Additional information is provided in [G.2](#).

Because the following CONNECTORS are inadequately specified, SMALL-BORE CONNECTORS for use in ENTERAL APPLICATIONS should not, but may connect with the following:

- the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;
- the temperature sensor and mating ports made in compliance with ISO 8185:2007, Annex DD;
- the nipples of EN 13544-2:2002 and EN 13544-2:2002+A1:2009.

The reference CONNECTORS for evaluation of the NON-INTERCONNECTABLE characteristics are described in [Annex C](#).

Where the design of the SMALL-BORE CONNECTOR of this part of ISO 80369 relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the NON-INTERCONNECTABLE characteristics shall be VERIFIED.

Check compliance by applying the tests of ISO 80369-1:2010, 5.1, and ISO 80369-1:2010, Annex B. Compliance also may be shown by applying a computer aided design (CAD) analysis of the dimensions of all of the ISO 80369 series SMALL BORE CONNECTORS and the SMALL BORE CONNECTOR under test, in conjunction with physical testing of the SMALL BORE CONNECTOR per [Annex B](#) where the CAD analysis does not demonstrate the NON-INTERCONNECTABLE characteristics. When necessary, the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with the NON-INTERCONNECTABLE characteristics test requirements of ISO 80369-1:2010, Annex B.

NOTE 1 MEDICAL DEVICES using the SMALL-BORE CONNECTORS of this part of ISO 80369 that do not rely on the dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics are presumed to comply with the NON-INTERCONNECTABLE characteristics test requirements of this part of ISO 80369.

NOTE 2 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in [Annex D](#).

NOTE 3 The summary of the usability requirements for ENTERAL SMALL-BORE CONNECTORS is provided in [Annex E](#).

NOTE 4 The summary of ENTERAL SMALL-BORE CONNECTORS criteria and requirements is provided in [Annex F](#).

NOTE 5 The summary of assessment of the design of ENTERAL SMALL-BORE CONNECTORS according to ISO 80369-1:2010, Clause 7, is contained in [Annex G](#).

4.2 Material used for ENTERAL SMALL-BORE CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, ENTERAL SMALL-BORE CONNECTORS shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 700 MPa.

Check compliance by applying the tests of ASTM D638-10 or ASTM D790-10.

4.3 TYPE TESTS

Compliance with the requirements of this part of ISO 80369 shall be determined by TYPE TESTS.

5 Dimensional requirements for ENTERAL SMALL-BORE CONNECTORS

ENTERAL SMALL-BORE CONNECTORS shall comply with the relevant dimensions and tolerances as given in

- [Figure B.1](#) and [Table B.1](#) for a male E1 CONNECTOR, and
- [Figure B.2](#) and [Table B.2](#) for a female E1 CONNECTOR.

Check compliance by verifying the dimensions and tolerances specified in [Annex B](#), as appropriate.

6 Performance requirements

6.1 Fluid leakage

6.1.1 Fluid leakage requirement

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for leakage using either the leakage by pressure decay TEST METHOD or the positive pressure liquid leakage TEST METHOD.

6.1.2 Leakage by pressure decay

ENTERAL SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the leakage by pressure decay TEST METHOD shall not leak by more than 0,005 Pa·m³/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium. MANUFACTURERS may use a greater applied pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference CONNECTOR specified in [Annex C](#).

6.1.3 Positive pressure liquid leakage

ENTERAL SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the positive pressure liquid leakage TEST METHOD shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa. MANUFACTURERS may use a greater applied pressure or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex C, while using the leakage reference CONNECTOR specified in [Annex C](#).

6.2 Stress cracking

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for stress cracking. ENTERAL SMALL-BORE CONNECTORS shall meet the requirements of [6.1.1](#) after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check compliance by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference CONNECTOR specified in [Annex C](#).

6.3 Resistance to separation from axial load

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for separation from axial load. ENTERAL SMALL-BORE CONNECTORS shall not separate from the reference CONNECTOR over a hold period between