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Enteral feeding systems — Design and testing

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Foreword

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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).

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

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This document was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in collaboration with ISO Technical Committee TC 84, *Devices for administration of medicinal products and catheters*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

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Introduction

Enteral feeding systems are intended to facilitate the delivery of enteral nutrition, medications and hydration to, or aspiration of gastric content from, humans. They are designed to pass enteral fluids or substances through the nose or mouth, or by gastrostomy, jejunostomy or oesophagostomy. Enteral feeding catheters are terminally placed in the stomach, duodenum, or jejunum.

The requirements and test methods of this document are specified so that, when used in current clinical practice, these medical devices do not compromise the clinical condition or the safety of patients.

Incidents have been reported of enteral fluids or substances being administered via incorrect routes, including intravenously and into the airway. An international effort has been made to reduce these incidents and two series of International Standards have been developed to provide application specific connectors:

— ISO 80369-3 specifies connectors intended for use between an enteral giving set, enteral extension sets, enteral syringes, enteral catheters, and enteral accessories;

— ISO 18250-3 specifies connectors intended for use between an enteral giving set, an enteral accessory and an enteral reservoir.

The use of these enteral-specific connectors has been specified in this document as well as small-bore connectors as specified in ISO 80369-1:2018, Clause 6.

ISO 80369-3 and ISO 18250-3 ensure that connectors for enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters and enteral accessories are unique and are not able to be connected to other small-bore connectors specified in the ISO 80369 series for the following applications: intravascular and hypodermic, breathing systems and driving gases, urethral and urinary, limb cuff inflation and neuraxial systems.

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The small-bore connectors and reservoir connectors, as defined in ISO 80369-3 and ISO 18250-3, respectively, for use in enteral applications should not, but may connect with the following connectors/ports in common use within the same environment:

— the cones and sockets of ISO 5356-1 and ISO 5356-2;

— the temperature sensor ports made in conformity with ISO 80601-2-74:2017, Annex EE;

— the nipples of EN 13544-2 and EN 13544-2+A1.

In this document, 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 document are as follows:

— "shall" means conformity with a requirement or a test is mandatory for conformity with this document,

— "should" means conformity with a requirement or a test is recommended but is not mandatory for conformity with this document, and

— "may" is used to describe a permissible way to achieve conformity with a requirement or test.

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Enteral feeding systems — Design and testing

1 Scope

This document specifies requirements for enteral feeding systems comprising enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters, and enteral accessories.

This document is not applicable to oral syringes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 7886-2:1996, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps*

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ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly process*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 18250-3:2018, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

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

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

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ASTM F640, *Standard Test Methods for Determining Radiopacity for Medical Use*

DIN 13273-7, *Catheter for medical use — Part 7: Determination of the x-ray attenuation of catheters; requirements and testing*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
distal end
end of the medical device furthest from the source of the nutrient or diet intended to be administered via an *enteral feeding catheter* (3.5)

Note 1 to entry: See Figure 1.

3.2
proximal end
end of the medical device closest to the source of nutrient or diet intended to be administered via an *enteral feeding catheter* (3.5)

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Note 1 to entry: See Figure 1.

3.3
enteral feeding system
system comprising the following enteral feeding devices: *enteral giving sets* (3.6), *enteral syringes* (3.8), *enteral feeding catheters* (3.5), and *enteral accessories* (3.4)

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3.4
enteral accessory
medical device that is used within the enteral system for the purposes of device placement or access of an enteral device; or for the purposes of filling, directing, stopping, or controlling flow of nutrients, medication, or aspirates

EXAMPLE Sheaths, guidewires, introducers.

3.5
enteral feeding catheter
indwelling tubular medical device to facilitate delivery or removal of fluids or substances into or from the gastrointestinal tract

3.6
enteral giving set
medical device for transferring enteral fluids or substances from an enteral reservoir to an *enteral feeding catheter* (3.5)

Note 1 to entry: Also known as enteral feeding sets.

Note 2 to entry: See Figure 1 for an example.

3.7
enteral extension set
medical device for transferring enteral fluids or substances from an *enteral giving set* (3.6) to an *enteral feeding catheter* (3.5)

Note 1 to entry: Also known as extension tubing.

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Note 2 to entry: See Figure 1 for an example.

3.8
enteral syringe
medical device for introduction or removal of fluids or substances into or from the gastrointestinal tract by means of pressure

Note 1 to entry: This does not include syringes for introducing fluids or substances directly into the mouth, i.e. oral-only syringes.

3.9
integral introducer
component that is attached to a percutaneous *enteral feeding catheter* (3.5) which is designed to facilitate initial catheter placement starting from inside the gastro-intestinal tract and ending outside the abdominal wall

4 General requirements

4.1 General

The following requirements apply to all components of the enteral feeding system unless superseded in the specific requirements in Clauses 5, 6, 7 and 8.

4.2 Risk management

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An established risk management process shall be applied to the design and development of the enteral feeding system.

NOTE ISO 14971 provides requirements and guidance for risk management of medical devices.

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Check conformity by inspection of the risk management file.

4.3 Usability

An established usability engineering process shall be applied to the design of the enteral feeding system to assess and mitigate risks caused by usability problems associated with correct use and use errors.

NOTE IEC 62366-1 provides requirements and guidance on the application of usability of medical devices.

Check conformity by inspection of the usability-engineering file.

4.4 Test methods

The medical device shall be tested in accordance with the test methods specified in Annexes B to J. Alternative test methods may be used if an equivalent degree of safety is obtained and the results of those alternative test methods can be related to the results obtained using the test methods specified in this document.

Check conformity by inspection of the technical file.

4.5 Materials

For certain materials, specific labelling and risk assessment requirements might apply, depending on national or regional regulations.

EXAMPLE Natural rubber latex, certain plasticizers used in polyvinyl chloride (PVC).

Check conformity by inspection of the technical file.

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4.6 Cleaning and disinfection

If not labelled for single use, the medical device shall be capable of being cleaned, disinfected, or sterilized, according to the manufacturer's instructions, without affecting the ability of the medical device to meet the requirements of this document throughout its claimed use life.

NOTE ISO 17664 provides requirements and guidance for information provided by the supplier for the processing of reusable medical devices.

Check conformity by inspection of the technical file.

4.7 Sterility

All devices supplied as "STERILE" shall be sterilized using a sterilization process that has been validated and is routinely controlled in accordance with an International Standard for the applicable method of sterilization to demonstrate achievement of a maximal sterility assurance level (SAL) of 10^{-6}, i.e. applicable parts of ISO 17665-1, ISO 11135, ISO 11137-1, ISO 25424 or ISO 14937.

Check conformity by inspection of the technical file.

4.8 Packaging

All medical devices supplied and marked as “STERILE” shall be contained in a packaging system conforming to ISO 11607-1 and ISO 11607-2.

Check conformity by inspection of the technical file.

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4.9 Biological safety

Enteral feeding systems shall be evaluated for biological safety in accordance with ISO 10993-1.

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Check conformity by inspection of the technical file.

4.10 Corrosion resistance

Any metallic component exposed to the patient or in contact with enteral fluids or substances shall be manufactured from corrosion resistant materials.

Check conformity by the test given in Annex B.

4.11 Surface finish

External surfaces of the parts of the enteral devices that are inserted into the body shall be free from extraneous matter and process and surface defects that can present an unacceptable risk of patient harm.

Check conformity by visual inspection by normal or corrected vision under a minimum 2,5 × magnification under an illuminance of 215 ± 5 lx.

4.12 Information supplied by the manufacturer

4.12.1 Marking

If present, markings on the devices shall be clearly legible and durable.

Check conformity by rubbing the markings, without undue pressure, with a cloth soaked in either ethanol or isopropanol.

Verify that the markings can be viewed from a distance of 50 cm ± 10 cm by an operator having a normal or corrected-to-normal vision.

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4.12.2 Symbols

Symbols should be used where appropriate and shall be in accordance with ISO 15223-1 or ISO 7000.

If symbols that are used are not defined in either of these International Standards, national or regional standards may be used or the symbols shall be described in the instructions for use (see 4.12.4 g).

Check conformity by inspection.

4.12.3 Labelling

The information provided on enteral feeding system labelling shall conform to relevant international and national requirements for those medical devices. The packaging (sterile barrier system and/or packaging system) shall be labelled with the following information as a minimum:

a) the name or trade name of the enteral feeding device;

b) the name and address of the manufacturer and, where appropriate, the name and address of the manufacturers' authorized representative;

c) the details necessary for the user to identify the enteral feeding device or contents of the packaging;

d) where appropriate, the word "STERILE" and the method used to sterilize the enteral feeding device;

e) the batch code, preceded by the word "LOT";

f) an indication of the date by which the enteral feeding device should be used, expressed at least as the year and month;

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g) any special storage or handling conditions;

h) if appropriate, an indication that the device is for single patient use (a manufacturer's indication of single use shall be consistent across its range).

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NOTE Applicable regulatory requirements for Unique Device Identifier (UDI) can apply.

4.12.4 Instructions for use

If present, the instructions for use shall include at least the following information:

a) where appropriate, an indication that the device is for single use or single patient use (a manufacturer's indication of single use shall be consistent across its range);

b) any special operating instructions required for safe and effective use of the device;

c) any specific warnings or precautions;

d) where applicable, the method of cleaning, disinfecting or sterilization necessary prior to use;

e) where applicable, Magnetic Resonance Imaging (MRI) compatibility information;

f) the date of issue or the revision level of the instructions for use;

g) where applicable, a description of any symbols used on the device or labelling (see 4.12.2 and 4.12.3).

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5 Additional requirements for enteral giving sets and enteral extension sets

5.1 General

Enteral giving sets and enteral extension sets shall consist of the following:

a) inlet port(s) or reservoir(s);

b) tubing;

c) outlet port.

Enteral giving sets may also include other features such as the following:

1) an access port;

2) a drip chamber;

3) a pump insert;

4) a means for regulating and/or stopping the flow through the enteral giving set.

See Figure 1.

5.2 Inlet ports

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5.2.1 The inlet port of an enteral giving set shall be:

a) a reservoir connector conforming to ISO 18250-3:2018, Figure B.1 and Table B.1 or Figure B.6 and Table B.6;

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b) a wide neck screw cap; or

c) a crown-cork cap.

NOTE 1 This does not apply if the reservoir is an integral part of the enteral giving set.

NOTE 2 Examples of screw caps and necks are defined in DIN 55525:1988, ASTM D2911-94 (reapproved 2001), DIN 6063-1:2011, DIN 6063-2:2011, DIN 168-1:1998. Examples of crown cork caps and necks are defined in DIN 6094-1:1982, ISO 12821, EN 14635.

5.2.2 The inlet port of an enteral extension set shall be:

a) a male enteral small-bore connector conforming to ISO 80369-3;

or alternatively

b) a connector conforming to ISO 80369-1.

5.3 Outlet ports

5.3.1 The outlet port of an enteral giving set shall be:

a) a female enteral small-bore connector conforming to ISO 80369-3; or alternatively;

b) a connector conforming to ISO 80369-1.

5.3.2 The outlet port of an enteral extension set shall be:

a) a female small-bore connector conforming to ISO 80369-3; or alternatively;

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b) a connector conforming to ISO 80369-1.

5.4 Access ports

If an access port of the enteral giving set is provided it shall be either:

a) a male connector conforming to ISO 80369-3;

or alternatively

b) a connector conforming to the requirements of ISO 80369-1.

5.5 Tensile strength

Enteral giving sets and enteral extension sets (including tubing, joints, and connections) shall withstand a tensile force of 15 N before breaking, becoming detached, or cracking.

Check conformity by the test method given in Annex C.

5.6 Leakage

5.6.1 Enteral giving sets shall not show signs of leakage sufficient to form a falling drop of water while being subjected to the internally applied pressure given in 5.6.2 and 5.6.3.

5.6.2 For enteral giving sets not designed for use with an enteral feeding pump, applied pressure shall be between 20 kPa and 22 kPa over a hold period of 30 s to 35 s.

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5.6.3 For enteral giving sets designed for use with an enteral feeding pump, applied pressure shall be:

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a) distal to the driving mechanism of the pump — between 200 kPa and 220 kPa or greater than the maximum operating pressure of the pump with which they are designed to be used over a hold period of 120 s to 130 s; and

b) proximal to the driving mechanism of the pump — between 20 kPa and 22 kPa over a hold period of 30 s to 35 s.

Check conformity by test method given in Annex D.

5.7 Additional information provided by the manufacturer

In addition to the general labelling requirements given in 4.12.3, enteral giving sets not designed to be used with an enteral feeding pump but designed for gravity use shall be labelled “for gravity use”.

Check conformity by visual inspection.

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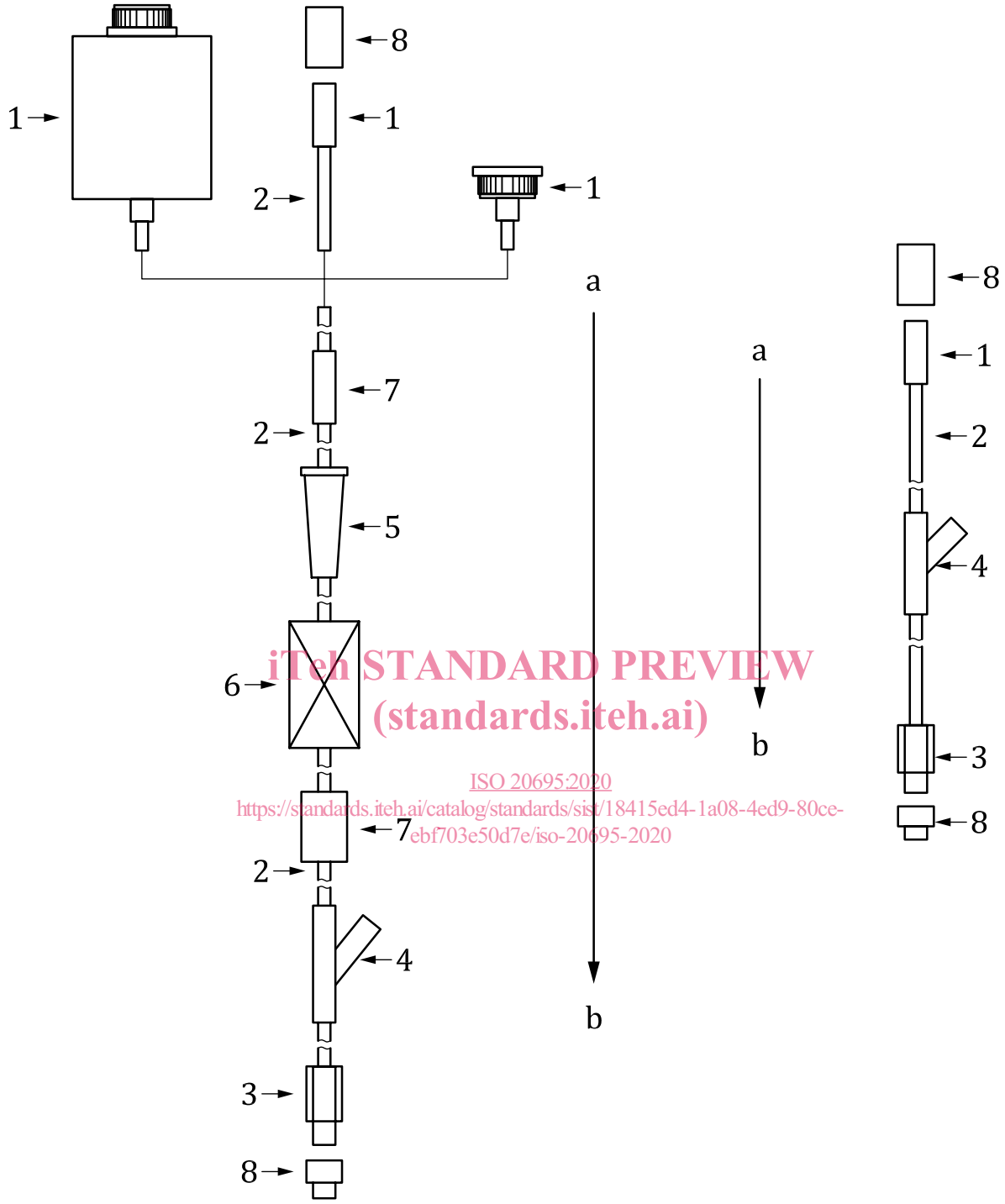

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Key

1	inlet port(s) or reservoir(s)	6	optional driving mechanism of the pump
2	tubing	7	optional means for regulating and/or stopping the flow
3	outlet port	8	optional dust cap or closure
4	optional access port	a	Proximal side of the enteral giving set/enteral extension set.
5	optional drip chamber	b	Distal side of the enteral giving set/enteral extension set.

Figure 1 — Example of enteral giving sets/extension sets with optional access port

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6 Additional requirements for enteral syringes

6.1 General

Enteral syringes shall consist of at least the following:

a) a graduated container;

b) unless the enteral syringe is designed for gravity use, there shall be a means to create pressure (e.g. a plunger or a bulb);

c) an outlet port.

6.2 Outlet port

The outlet port of an enteral syringe shall be either:

a) a female connector conforming to ISO 80369-3; or

b) a connector conforming to the requirements of ISO 80369-1.

NOTE An example of an alternative enteral syringe tip is provided in Annex K.

6.3 Enteral syringe requirements

Enteral syringes shall conform to ISO 7886-1:2017 and ISO 7886-2:1996 as listed in Tables 1 and 2.

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Table 1 — Enteral syringe requirements in accordance with ISO 7886-1:2017

Clause/subclause	Subject	Applicability
5	General requirements	All syringe types
6.2	Limits for acidity or alkalinity	All syringe types
6.3	Limits for extractable metals	All syringe types
7	Lubricant	Only for syringes with a plunger
8	Tolerance on graduated scale	All syringe types
9	Graduated scale	All syringe types
10	Barrel	Only for syringes with a plunger
11	Plunger stopper/plunger assembly	Only for syringes with a plunger
12.2	Position of nozzle on end of barrel	All syringe types
13.2	Freedom from air and liquid leakage past plunger stopper	Only for syringes with a plunger
13.3	Force to operate the piston	Only for syringes with a plunger

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