BS ISO 8600-1:2015

BSI Standards Publication

Endoscopes — Medical endoscopes and endotherapy devices

Part 1: General requirements

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National foreword

This British Standard is the UK implementation of ISO 8600-1:2015. It supersedes BS ISO 8600-1:2013 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CPW/172, Optics and Photonics.

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Part 1: General requirements

Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie — Partie 1: Exigences générales

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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.

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).

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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 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

This fourth edition cancels and replaces the third edition (ISO 8600-1:2013), of which it constitutes a minor revision in order to update the definition and the corresponding Figure 1 for the term "field of view".

ISO 8600 consists of the following parts, under the general title *Endoscopes — Medical endoscopes and endotherapy devices*:

— *Part 1: General requirements*

— *Part 2: Particular requirements for rigid bronchoscopes*

— *Part 3: Determination of field of view and direction of view of endoscopes with optics*

— *Part 4: Determination of maximum width of insertion portion*

— *Part 5: Determination of optical resolution of rigid endoscopes with optics*

— *Part 6: Vocabulary*

— *Part 7: Basic requirements for medical endoscopes of water-resistant type*

INTERNATIONAL STANDARD **ISO 8600-1:2015(E)**

Endoscopes — Medical endoscopes and endotherapy devices —

Part 1: General requirements

1 Scope

This part of ISO 8600 gives definitions of terms and requirements for endoscopes and endotherapy devices used in the practice of medicine.

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 8600–3, *Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 3: Determination of field of view and direction of view of endoscopes with optics*

ISO 8600–4, *Endoscopes — Medical endoscopes and endotherapy devices — Part 4: Determination of maximum width of insertion portion*

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

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

IEC 60601–2–18, *Medical electric equipment — Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

3 Terms and definitions

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

3.1
endoscope
medical instrument having viewing means, with or without optics, introduced into a body cavity through a natural or surgically created body opening for examination, diagnosis, or therapy

Note 1 to entry: Endoscopes may be of rigid or flexible type; all types may have different image pick-up systems (e.g. via lenses or ultrasonic sensors) and different image-transmitting systems (e.g. optical, via lenses, or fibre bundles, or electrical).

Note 2 to entry: See also ISO 8600-6.

3.2
endotherapy device
medical device intended to be inserted into a natural or surgically created body opening during endoscopic procedures, whether through the same or a different orifice from the *endoscope* (3.1) for examination, diagnosis, or therapy

Note 1 to entry: Endotherapy devices include the instrument to create the body opening and through which an *endoscope* (3.1) or endotherapy device is inserted, such as a guide tube, trocar pin, trocar sleeve, or sliding tube. Endotherapy devices include the devices to be inserted through the openings other than the opening for an *endoscope* (3.1), to ensure the safety of the devices for the intended use under the endoscopic view.

Note 2 to entry: See also ISO 8600-6.

3.3
rigid endoscope (endotherapy device)
endoscope (3.1) or *endotherapy device* (3.2) whose insertion portion is intended to be unyielding to natural or surgically created body cavities or *instrument channels* (3.8)

Note 1 to entry: See also ISO 8600-6.

3.4
flexible endoscope (endotherapy device)
endoscope (3.1) or *endotherapy device* (3.2) whose insertion portion is intended to conform to natural or surgically created body cavities or *instrument channels* (3.8)

Note 1 to entry: See also ISO 8600-6.

3.5
French
Charrière
Fr
measure of the size of certain circular or non-circular cross-section endoscopes defined as

$$Fr = 3u/\pi$$

where

u is the perimeter of the cross-section, expressed in millimetres

Note 1 to entry: See also ISO 8600-6.

3.6
distal
any location of that portion of an *endoscope* (3.1) or *endotherapy device* (3.2) which is farther from the user than some referenced point

Note 1 to entry: See also ISO 8600-6.

3.7
proximal
any location of that portion of an *endoscope* (3.1) or *endotherapy device* (3.2) which is closer to the user than some referenced point

Note 1 to entry: See also ISO 8600-6.

3.8
instrument channel
portion of an *endoscope* (3.1) or *endotherapy device* (3.2) through which an endoscope or an endotherapy device is intended to pass

Note 1 to entry: See also ISO 8600-6.

3.9
insertion portion
insertion tube
portion of an *endoscope* (3.1) or *endotherapy device* (3.2) which is intended to be inserted into a natural or surgically created body opening or which is intended to be inserted into the *instrument channel* (3.8) of an *endoscope* (3.1) or endotherapy device

Note 1 to entry: See also ISO 8600-6.

3.10
maximum insertion portion width
maximum external width of an *endoscope* (3.1) or *endotherapy device* (3.2) throughout the length of the *insertion portion* (3.9) to be inserted

Note 1 to entry: The maximum width of any expandable or transformable portion of the insertion portion is not considered as a maximum insertion portion width, such as balloons, controllable parts, jaws and the like having variable insertion portion widths.

Note 2 to entry: See also ISO 8600-6.

3.11
minimum instrument channel width
minimum internal width of an *instrument channel* (3.8)

Note 1 to entry: See also ISO 8600-6.

3.12
working length
length of the *insertion portion* (3.9) stated in the instruction manual

Note 1 to entry: See also ISO 8600-6.

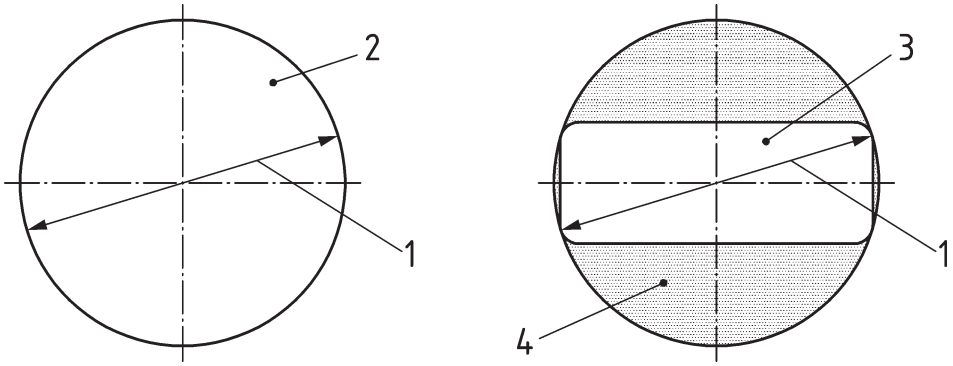
3.13
field of view
view of an *endoscope* (3.1) with optics as stated by the manufacturer or distributor

Note 1 to entry: The field of view is not appropriate when the endoscope is intended to be in contact with the object.

Note 2 to entry: For non-circular images, the field of view may be the largest visible circle.

Note 3 to entry: See Figure 1.

Note 4 to entry: See also ISO 8600-6.



Key

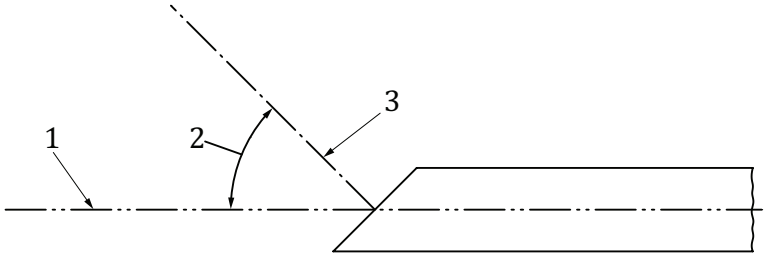
1 field of view
2 visible area of a circular image
3 visible area of a non-circular image
4 non-visible area of a non-circular image

Figure 1 — Field of view

3.14
direction of view
location of the centre of the object field relative to the normal axis of the *endoscope* (3.1), expressed as the angle (in degrees) between the normal axis of the endoscope (0°) and the central axis of the *field of view* (3.13)

Note 1 to entry: See Figure 2.

Note 2 to entry: See also ISO 8600-6.



Key

1 endoscope normal axis
2 direction of view
3 central axis of field of view

Figure 2 — Direction of view

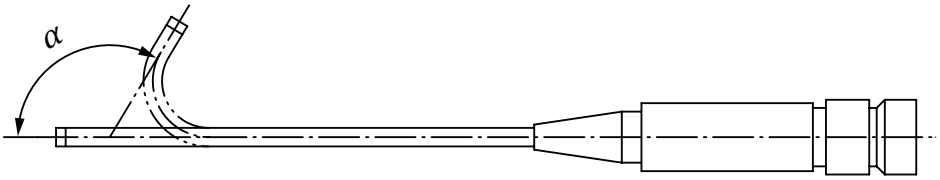
3.15
controllable portion
part of the *insertion portion* (3.9) of an *endoscope* (3.1) or *endotherapy device* (3.2) whose motion is intended to be remotely controlled by the user

Note 1 to entry: See also ISO 8600-6.

3.16
fitting/connector for liquid or gaseous media
port for input/injection or output/suction of liquid or gaseous media on *endoscopes* (3.1) or *endotherapy devices* (3.2)

3.17
angle of deflection
α
angle between the centre line of the straightened *insertion portion* (3.9) and the centre line of the deflected *distal* (3.6) tip when deflection control system is operated

Note 1 to entry: See Figure 3.



Key
α angle of deflection

Figure 3 — Angle of deflection

4 Requirements

4.1 General

Design and construction of endoscopes and endotherapy devices shall comply with the following requirements.

4.2 Surface and edges

Endoscopes and endotherapy devices shall be designed in such a way that their intended use will not lead to any unintentional injuries.

The surfaces of all endoscopes and endotherapy devices shall be free of pores, cracks, and remainders of tooling agents.

4.3 Maximum insertion portion width

The maximum insertion portion width shall not be larger than that stated in the instruction manual [see Clause 7 e) 3)].

4.4 Minimum instrument channel width

The minimum instrument channel width shall not be smaller than that stated in the instruction manual [see Clause 7 e) 4)].

4.5 Field of view

If not otherwise specified by the manufacturer, the deviation of the field of view of an endoscope with optics from the value stated by the manufacturer or distributor shall not be greater than 15 %.

4.6 Direction of view

If not otherwise specified by the manufacturer, the deviation of the direction of view of a rigid endoscope with optics from the value stated in the instruction manual shall not be greater than 10°.

4.7 Safety

Endoscopes and endotherapy devices shall conform to IEC 60601-2-18.

4.8 Biological compatibility

Materials used for the outer surface of the insertion portion shall be evaluated for biological compatibility in accordance with ISO 10993-1.

4.9 Fittings/connectors for liquid or gaseous media

Depending on their utilization, endoscopes and endotherapy devices shall be provided with fittings for input or output of liquid or gaseous media. The manufacturer of endoscopes and endotherapy devices shall carry out a risk management procedure in accordance with ISO 14971 to consider the probability of misconnection of medical devices intended for connection to endoscopes or endotherapy devices to non-endoscopic patient connections (e.g. intravenous applications).

The purpose of a risk management procedure is to assess both the physical possibility of a misconnection of such medical devices to non-endoscopic patient connections, particularly to Luer connectors in accordance with ISO 594-1 and ISO 594-2, and the probability of occurrence of such a misconnection, together with the potential severity of harm for the patient. Where relevant standards exist for connectors that match the intended use of the endoscope, endotherapy device or medical device intended for connection to endoscopes or endotherapy devices, these should be used unless contra-indicated by the risk management procedure.

Guidelines on the application of risk management to endoscopic system connectors are given in Annex A for information.

4.10 Deflection control system for the controllable portion

4.10.1 General

If the endoscope has a hand wheel (knob type) deflection control system for the controllable portion and if the hand wheel(s) are located on the right hand side of the proximal part/control body (from the user's point of view), then the deflection control system shall fulfil the conditions given in 4.10.2 to 4.10.5.

If the endoscope has a deflection control system other than what is described below, the endoscope shall have labelling indicating the direction in which the controller moves and the corresponding direction of the deflection of the controllable portion.

NOTE Hand wheel deflection control system means a deflection control system with a knob type wheel rotated by the user's hand.

4.10.2 Deflection up and down

When the insertion portion is in a straight position and the hand wheel for up-down deflection is moved anticlockwise, the controllable portion shall be deflected up, and vice versa. See Figure 4 a).

4.10.3 Deflection right and left

When the insertion portion is in a straight position and the hand wheel for right-left deflection is moved anticlockwise, the controllable portion shall be deflected to the left, and vice versa. See Figure 4 b).

4.10.4 Arrangement of the hand wheels

If the hand wheels for up-down deflection and right-left deflection are arranged on a common axis, the hand wheel for right-left deflection shall be positioned on the far side from the control body. See Figure 4 c).

4.10.5 Maximum angle of deflection

When the insertion portion is in a straight position, the angle of deflection when the control system is operated maximally shall not deviate more than 15° from the value stated in the instruction manual.

5 Testing

5.1 General

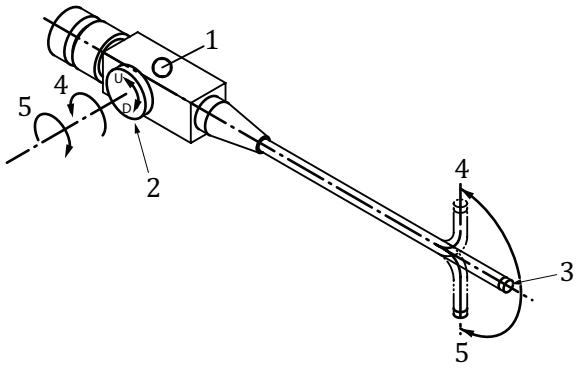
All tests described in this part of ISO 8600 are type tests.

5.2 Surface and edges

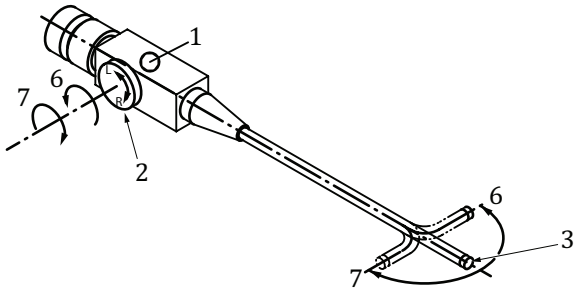
The compliance of an endoscope or endotherapy device with the requirements of 4.2 shall be judged visually and subjectively, without magnifying aids and with sufficient illumination.

5.3 Maximum insertion portion width

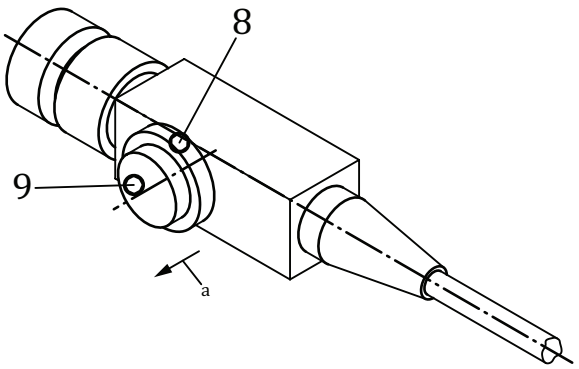
The maximum insertion portion width shall be determined in accordance with ISO 8600-4.



a) Hand wheel up-down deflection control system for controllable portion



b) Hand wheel right-left deflection control system for controllable portion



c) Arrangement of hand wheels for up-down deflection and right-left deflection

Key

1	control body	6	left
2	hand wheel	7	right
3	distal end	8	up/down
4	up	9	right/left
5	down	a	Far side.

Figure 4 — Hand wheels for up-down deflection and right-left deflection

5.4 Minimum instrument channel width

For the determination of minimum instrument channel width, the measuring instrument shall have an accuracy of greater than 0,01 mm.

5.5 Field of view

The field of view of an endoscope with optics shall be determined in accordance with ISO 8600-3.

5.6 Direction of view

The direction of view of an endoscope with optics shall be determined in accordance with ISO 8600-3.

6 Marking

6.1 Minimum marking

Each individual endoscope or endotherapy device shall have the following minimum marking:

a) model number and/or other mark sufficient to identify the endoscope or endotherapy device and its manufacturer;

b) maximum insertion portion width, minimum instrument channel width, working length, field of view, and/or direction of view where such identification is necessary for the intended use of the endoscope or endotherapy device. The insertion portion width and instrument channel width units shall be in millimetres. The insertion portion width and instrument channel width can also be marked in French size as defined in 3.5, shown by either "*Fr*" or an encircled number;

c) wherever reasonable and practicable, the endoscope or endotherapy device and detachable component(s) shall be identified in terms of lot numbers or serial numbers, etc.

6.2 Marking legibility

The marking shall remain legible over the lifetime of the device when the endoscope or endotherapy device is used, cleaned, disinfected, sterilized and stored in accordance with the instruction manual.

6.3 Marking exceptions

When marking on the endoscope or endotherapy device or detachable component(s) is impossible to achieve due to size or configuration, the required marking shall be part of the packaging or part of the accompanying instruction manual.

7 Instruction manual

The instruction manual for endoscopes or endotherapy devices shall contain at least the following information:

a) identification, including the following:

   1) manufacturer's or distributor's name and address;

   2) model number and name;

b) statement of the intended uses;

c) instructions on the functions and proper use;

d) annotated illustration, as appropriate, to permit the user to identify pertinent parts and characteristics which are referenced in the instruction manual, and are consistent with Clause 3;

e) specifications, including the following:

   1) direction of view;

   2) field of view, if specified;

   3) maximum insertion portion width and working length; the following precaution shall be given in the instruction manual, if necessary: "There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination.";

   4) minimum instrument channel width; the following precaution shall be given in the instruction manual, if necessary: "There is no guarantee that instruments selected solely using this minimum instrument channel width will be compatible in combination.";

f) remote controls and associated controllable portion positions available to the user;

g) instructions as required for assembling for its intended use, and for the disassembling and reassembling after cleaning, disinfection, and/or sterilization processes;

h) precautions and instructions applicable to the intended use, including those related to electrical, electronic, electro-optical, electro-medical, or electro-acoustical apparatus intended to be used with the endoscope or endotherapy device and in conformance with IEC 60601-2-18;

   1) any permitted liquids intended to be used with the endoscope, e.g. contrast medium, sclerosing therapy medium, lubricant and anaesthetic medium, and warnings concerning the usage of liquids not mentioned here;

   2) precautions for use in flammable atmospheres;

i) inspection instructions to provide reasonable assurance that the endoscope and endotherapy device are in working order;

j) instructions for the cleaning of reusable endoscopes and endotherapy devices and identification of any specific cleaning tools or equipment;

k) instructions for the specific disinfection and sterilization environments in which the equipment can survive;

l) recommended procedures for storage prior to use and, for reusable equipment, procedures for storage between uses;

m) identification of any user-replaceable parts and instructions for their replacement;

n) identification of where the user can obtain authorized service.

8 Packaging

The manufacturer should package the endoscope or endotherapy device so as to protect the endoscope or endotherapy device from damage by the adverse effects of storage and shipping environments.

Annex A
(informative)

Guidelines on the application of risk management to endoscopic system connector

A.1 As stated in 4.9, the manufacturer of the endoscope or endotherapy device will have to carry out a risk management procedure in accordance with ISO 14971 to consider the probability of misconnection of medical devices intended for connection to endoscopes or endotherapy devices to non-endoscopic patient connections (e.g. intravenous applications).

The purpose of the risk management procedure is to assess both the physical possibility of a misconnection of such medical devices to non-endoscopic patient connections, particularly to Luer connectors in accordance with ISO 594-1 and ISO 594-2, and the probability of occurrence of such a misconnection, together with the potential severity of harm for the patient. Where relevant standards exist for connectors that match the intended use of the endoscope, endotherapy device or medical device intended for connection to endoscopes or endotherapy devices, these should be used unless contra-indicated by the risk management procedure.

This Annex provides guidance for manufacturers of endoscopes, endotherapy devices and medical devices intended for connection to endoscopes and endotherapy devices in assessing the level of risk associated with connectors in endoscopy systems related to their intended use, where specific connectors in accordance with relevant standards do not exist.

A.2 As outlined in ISO 14971:2007, Annex E, risk estimation for medical devices should be accomplished by combining two components:

— probability of occurrence of harm, i.e. how often the harm can occur;

— consequences of that harm, i.e. how severe it can be.

Where possible, the estimation of probability of occurrence should be based on quantitative data, but if there is no such data, then a qualitative approach should be taken, commonly involving the prediction of probability using analytical or simulation techniques, and/or the use of expert judgement.

The severity of harm will generally be easier to quantify, perhaps distinguishing between only three or four levels.

The acceptability of risk is generally recognized to fall into three categories:

a) broadly acceptable;

b) as low as reasonably possible (ALARP);

c) intolerable.

A.3 When considering endoscopy system connectors, the manufacturer's risk analysis should include consideration of "probability" and "severity" of at least the following factors:

a) cross-connection within the endoscopy system;

b) misconnection to unrelated patient connections;

c) misconnection to unrelated medical equipment;

d) security of connection under normal and single-fault conditions;

e) intended use of connector (e.g. dedicated or multi-use);

f) reprocessing of reusable connectors.

In making an assessment of the probability of such possible events, consideration should also be given to other factors of use, including the following:

— intended or anticipated location of use (e.g. use in an intensive care facility, where a number of patient connections are probable, can present higher risks of misconnection than use in an endoscopy suite);

— whether it is normal for patient connections to be covered/hidden from immediate view for the intended procedure;

— proximity of the endoscopy system connections to other probable patient connections;

— whether use of the connector is intended to take place inside or outside the patient environment;

— whether patient connections made during the endoscopy procedure remain in place after the procedure;

— whether it is possible/impossible for the connector to reach the patient in normal use/single fault condition;

— normal level of supervision/staffing associated with the procedure.

For reusable devices, the risks of changing from the status quo should also be assessed, including any transitional provisions that might be necessary if equipment with “new” connectors is expected to be used safely in combination with equipment that has “old” connectors.

Where, following application of risk management in accordance with ISO 14971, a manufacturer decides to use a Luer connector in accordance with ISO 594-1 and ISO 594-2, then it is advisable to record a full justification for this decision in the risk management file, as misconnection of endoscope supply lines (e.g. insufflating gas, suction, irrigation fluid) and substances delivered via syringes (e.g. air, water, contrast media, topical anaesthetic, sclerosant, mucosa staining fluid) can prove fatal if misconnected to particular non-endoscopic patient ports (such as high pressure gas insufflation to the vascular system).

Bibliography

[1] ISO 594-1, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

[2] ISO 594-2, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

[3] ISO 8600-6, *Optics and photonics — Medical endoscopes and endotherapy devices — Part 6: Vocabulary*

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