INTERNATIONAL STANDARD

ISO 8600-1

Third edition
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Endoscopes — Medical endoscopes and endotherapy devices —

Part 1: General requirements

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

Reference number
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Contents

Page

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 8600-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

This third edition cancels and replaces the second edition (ISO 8600-1:2005), which has been technically revised.

ISO 8600 consists of the following parts, under the general title *Endoscopes — Medical endoscopes and endotherapy devices*[1)]:

— *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*

1) This title will be used uniformly after the systematic review of all parts of ISO 8600. At present Parts 1, 5 and 6 have the title *Optics and photonics — Medical endoscopes and endotherapy devices*; Parts 2 and 3 have the title *Optics and optical instruments — Medical endoscopes and endoscopic accessories*; Part 4 has the title *Optics and optical instruments — Medical endoscopes and certain accessories*.

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 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 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 certain accessories — 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 14971:2007, *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.