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Endoscopes — Medical endoscopes and endotherapy devices —

Part 8: Particular requirements for capsule endoscopes

Endoscopes — Endoscopes médicaux et dispositifs d'endothérapie — Partie 8: Exigences particulières pour les endoscopes à capsule

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Foreword

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC172, *Optics and photonics*, Subcommittee SC 5,*Microscopes and endoscope*s.

A list of all parts in the ISO 8600 series can be found on the ISO website.

Endoscopes — Medical endoscopes and endotherapy devices —

Part 8: Particular requirements for capsule endoscopes

1 Scope

This document applies to capsule endoscopes used for clinical practice. The document defines relevant terms and gives requirements for them.

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 8600-1:2015, *Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements*

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

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8600-1, ISO 8600-6 and the following 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
maximum diameter
maximum diameter at all cross sectional surfaces which is perpendicular to the longer axis of capsule-shaped body

Note 1 to entry: Note to entry 1: The maximum diameter is measured in millimetres.

3.2
maximum length
maximum length at the longer axis of capsule-shaped body

Note 1 to entry: Note to entry 1: The maximum length is measured in millimetres.

3.3
recording time
time in which observation images can be recorded under the environments stated in the instruction manual