

ISO 8600-1:2015-10 (E)

Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements

Contents		Page
Foreword		iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	5
4.1	General	5
4.2	Surface and edges	5
4.3	Maximum insertion portion width	5
4.4	Minimum instrument channel width	5
4.5	Field of view	5
4.6	Direction of view	5
4.7	Safety	6
4.8	Biological compatibility	6
4.9	Fittings/connectors for liquid or gaseous media	6
4.10	Deflection control system for the controllable portion	6
4.10.1	General	6
4.10.2	Deflection up and down	6
4.10.3	Deflection right and left	6
4.10.4	Arrangement of the hand wheels	6
4.10.5	Maximum angle of deflection	7
5	Testing	7
5.1	General	7
5.2	Surface and edges	7
5.3	Maximum insertion portion width	7
5.4	Minimum instrument channel width	8
5.5	Field of view	8
5.6	Direction of view	8
6	Marking	8
6.1	Minimum marking	8
6.2	Marking legibility	9
6.3	Marking exceptions	9
7	Instruction manual	9
8	Packaging	10
Annex A (informative)	Guidelines on the application of risk management to endoscopic system connector	11
Bibliography		13