

ISO 10555-1:2023-11 (E)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements

Contents		Page
Foreword		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	5
4.1	Risk approach	5
4.2	Usability engineering	5
4.3	Sterilization	5
4.4	Shelf life	5
4.5	Detectability	5
4.6	Biocompatibility	5
4.7	Surface	5
4.8	Corrosion resistance	6
4.9	Peak tensile force	6
4.10	Freedom from leakage during pressurization	7
4.11	Freedom from leakage during aspiration	7
4.12	Hubs	7
4.13	Flowrate	8
4.14	Power injection burst pressure	8
4.15	Packaging system	8
4.16	Simulated use, kink and/or torque testing to consider depending on device design, intended use, and risk analysis	8
4.17	Coating integrity and/or particulate testing to consider depending on device design, intended use, and risk analysis	9
4.18	Distal tip stiffness testing to consider for neurovascular applications	9
5	Designation of nominal size	9
5.1	Nominal outside diameter	9
5.2	Nominal inside diameter	9
5.3	Nominal effective length	9
6	Information to be supplied with the catheter	10
6.1	General	10
6.2	Marking on the device and/or primary packaging	10
6.3	Instructions for use	11
6.4	Marking on the secondary packaging	11
Annex A (normative)	Test method for corrosion resistance	12
Annex B (normative)	Method for determining peak tensile force	13
Annex C (normative)	Test method for liquid leakage under pressure	16
Annex D (normative)	Test method for air leakage into hub assembly during aspiration	18
Annex E (normative)	Determination of flow rate through catheter	20

Annex F (normative) Test for burst pressure under static conditions	22
Annex G (normative) Power injection tests for flowrate and device pressure (only for products indicated for power injection)	25
Annex H (informative) Units of measurement systems other than those specified in this document	30
Annex I (normative) Test method for air leakage under water	32
Annex J (informative) Rationale and guidance	34
Annex K (informative) Test methods for distal tip stiffness for neurovascular applications	41
Bibliography	43