

ISO 18250-1:2018-12 (E)

Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 1: General requirements and common test methods

Contents		Page
Foreword		iv
Introduction		vi
1	*Scope	1
2	Normative references	2
3	Terms and definitions	2
4	Materials used for reservoir connectors	4
4.1	*General	4
4.2	Alternative test methods	4
5	*Requirements for reservoir connectors for specific applications	4
5.1	*Reservoir connector incompatibility	4
5.2	Enteral applications	5
5.3	Neural applications	5
5.4	Intravascular applications	5
5.5	Citrate-based anticoagulant solution for apheresis applications	5
7	*Performance requirements	5
7.1	Leakage	5
7.1.1	Positive-pressure liquid leakage	5
7.1.2	Sub atmospheric pressure air leakage	6
7.2	Stress-cracking	6
7.3	Resistance to separation from axial load	6
7.4	Resistance to separation from unscrewing	6
7.5	Resistance to overriding	6
7.6	Disconnection by unscrewing for floating or rotating screw-thread locking connectors and locking connectors with fixed threads	6
Annex A (informative)	Rationale and guidance	7
Annex B (normative)	test methods for demonstrating non-interconnectable characteristics	14
Annex C (normative)	*Positive pressure liquid leakage test method	28
Annex D (normative)	*Sub-atmospheric-pressure air leakage test method	31
Annex E (normative)	*Stress cracking test method	35
Annex F (normative)	*Resistance to separation from axial load test method	37
Annex G (normative)	*Resistance to separation from unscrewing test method	39
Annex H (normative)	*Resistance to overriding test method	41
Annex I (normative)	*Disconnection by unscrewing test method for floating or rotating screw-thread locking connectors and locking connectors with fixed threads	43

Annex J (informative)*Modificationofthetestmethods to generate variable data for statistical analysis	45
Annex K (informative) Examples of medicaldevices on which reservoirconnectors may be used for each application category	48
Annex L (informative) Alternative mechanical testmethods	49
Bibliography	50
Terminology--Alphabeticalindexofdefinedterms	52