

Guidance to the required reference connectors and equipment for testing connectors for reservoir delivery systems for healthcare applications - Citrate-based anticoagulant solution for apheresis applications

ISO 18250-8:2018 Reference Connectors and ISO 80369-20:2015 Test Equipment			
ISO 18250-8 Clause	Required Test Method Annex of ISO 80369-20	Enersol equipment required	Required Enersol reference connectors for testing AC Reservoir connectors
Clause 5 - all sub-clauses	Annex B through I requires the assembly of the appropriate reference connector with the test sample, using a specified force and torque to assemble them.	S15B - Connector assembly device	Any/all reference connectors (S89-S93)
Clause 5.2 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S72 - Fig. C.1 MC for testing FC S73 - Fig. C.1 FC for testing MC
Clause 5.3 - Stress cracking	Annex E - Stress cracking	Use S15B and S16B	S72 - Fig. C.1 MC for testing FC S73 - Fig. C.1 FC for testing MC
Clause 5.4 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18B - Separation force device	S74 - Fig. C.5 MC for testing FC S75 - Fig. C.6 FC for testing MC
Clause 5.5 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S72 - Fig. C.1 MC for testing FC S73 - Fig. C.1 FC for testing MC
Clause 5.6 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S74 - Fig. C.5 MC for testing FC S75 - Fig. C.6 FC for testing MC
Clause 5.7 - Subatmospheric pressure air leakage	Annex D - Subatmospheric pressure air leakage	S78 or S78B - Automated subatmospheric pressure air leakage tester	S72 - Fig. C.1 MC for testing FC S73 - Fig. C.1 FC for testing MC
KEY: FC = Female Connector MC = Male Connector			