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QUALITY ASSURANCE TESTING, EQUIPMENT AND SERVICES

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Guidance to the required reference connectors and equipment for testing (Luer) small-bore connectors for intravascular or hypodermic applications

ISO 80369-7:2016 & 2021 Reference Connectors and ISO 80369-20:2015 Test Equipment			
ISO 80369-7 Clause	**ISO 80369-20 Annex**	**Enersol equipment required**	**Requried Enersol reference connectors for testing (Luer) intravascular/hypodermic small-bore connectors**
Clause 6 - all sub-clauses	The test methods require the test sample is assembled with the appropriate reference connector, using a specified force and/or torque to assemble them.	S15B - Connector assembly device	Any/all reference connectors listed below
Clause 6.1.1 - Fluid leakage requirement	Evaluate using EITHER leakage by pressure decay, or positive pressure liquid leakage. It is inferred the same method is used after the stress cracking conditioning.		
Clause 6.1.2 - Leakage by pressure decay	Annex B - Leakage by Pressure Decay	S77 or S77B - Automated pressure decay tester	S07 - Fig. C.1 - Lock - SC for testing CC S09 - Fig. C.4 - Lock - CC for testing SC S11 - Fig. C.2 - Slip - CC for testing SC S12 - Fig. C.5 - Slip - SC for testing CC
Clause 6.1.3 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S07 - Fig. C.1 - Lock - SC for testing CC S09 - Fig. C.4 - Lock - CC for testing SC S11 - Fig. C.2 - Slip - CC for testing SC S12 - Fig. C.5 - Slip - SC for testing CC
Clause 6.2 - Subatmospheric pressure air leakage***	Annex D - Subatmospheric pressure air leakage***	S78B - Automated subatmospheric pressure air leakage tester*** Or for locations 900m or more above sea level, the S78H is required for this test	S07 - Fig. C.1 - Lock - SC for testing CC S09 - Fig. C.4 - Lock - CC for testing SC S11 - Fig. C.2 - Slip - CC for testing SC S12 - Fig. C.5 - Slip - SC for testing CC
Clause 6.3 - Stress cracking	Annex E - Stress cracking	Use S15B and; S16B for positive pressure liquid leakage or S77/S77B for pressure decay	S07 - Fig. C.1 - Lock - SC for testing CC S09 - Fig. C.4 - Lock - CC for testing SC S11 - Fig. C.2 - Slip - CC for testing SC S12 - Fig. C.5 - Slip - SC for testing CC
Clause 6.4 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18B - Separation force device	S08 - Fig. C.3 - Lock - SC for testing CC S10 - Fig. C.6 - Lock - CC for testing SC S11 - Fig. C.2 - Slip - CC for testing SC S12 - Fig. C.5 - Slip - SC for testing CC
Clause 6.5 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S07 - Fig. C.1 - Lock - SC for testing CC S09 - Fig. C.4 - Lock - CC for testing SC Test not required for slips
Clause 6.6 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S08 - Fig. C.3 - Lock - SC for testing CC S10 - Fig. C.6 - Lock - CC for testing SC Test not required for slips
KEY: SC = Socket (Female) Connector CC = Cone (Male) Connector			
*** = NOTE: For laboratories located at 600m-899m or at 900m or more above sea level, please let Enersol know as this affects the S78B units where 80-88kPa subatmospheric pressure is required.			