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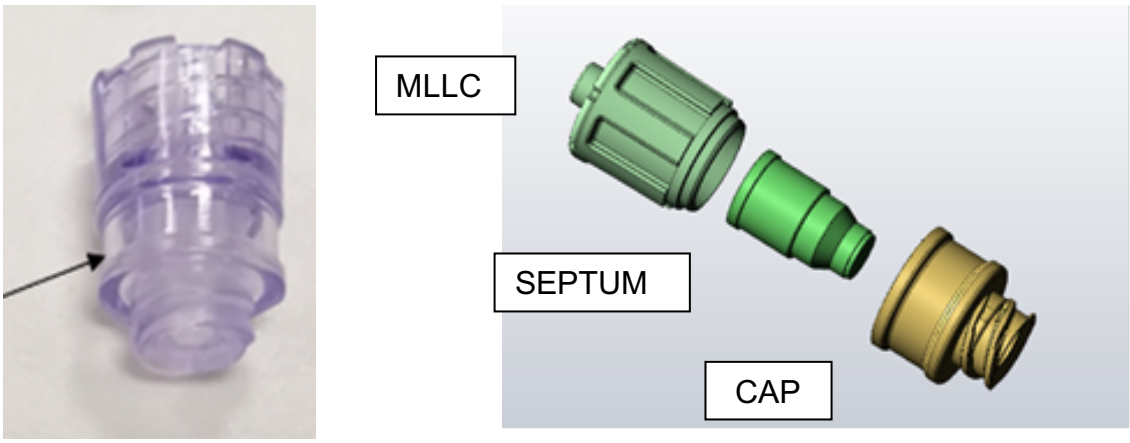
1. Summary

1.1. Dow Corning, the supplier of the TSL097 Silicone QP1 50 LSR (Liquid Silicone Rubber), has informed Haemopharm (Bonini) about the discontinuation of this LSR raw material. Haemopharm decided to replace it with raw material SILPURAN® 6000/50 A+B which is produced by Wacker for the new septum NIP Elcam PN 590422. Haemopharm (Bonini) is also the producer of the current septum LSR NIP Elcam PN: 590408.

Picture # 1: NIP Stand Alone Luer Activated Valve



1.2. The current silicone septum valve PN 590408 is used as a LAV (**L**uer **a**ctivated **v**alve) in the nip stand-alone assembly PN: 220808 and other LAV Products.

1.3. Haemopharm informed EMIT that they are willing to produce 7 million LSR NIPs from the QP1 50, before they move to the new LSR NIP from SILPURAN® 6000/50.

1.4. According to EMIT forecast, 7 million NIPs will allow us to continue producing with the current QP1-50 LSR until June-2025.

1.5. Elcam CCB decided in ECO-24-0005 that since Elcam has the responsibility for the design of the Stand-alone NIP, even though the final product is produced at EMIT, it is required to perform repeated verification test for the product with the new LSR component injected from SILPURAN® 6000/50 (NIP 590422).

1.6. According to the CCB decision, PRJ-0695-Silicon Change on NIP valve was opened at Elcam.

1.7. The project includes:

1.7.1. Assembly of products with new and old LSR materials at EMIT.

1.7.2. Verification test plan including sterilization and accelerated aging, tests and report which compares between the functional performances of products assembled with the new and old LSR materials.

1.7.3. Other activities according to FMEA outputs.

1.8. Process validation for products 220808L, 220808F0, 220808M0 and 220808F00 with the new valve will be done by EMIT and is not included in PRJ-0695. The validation process in EMIT is scheduled to be completed by the end of April.

1.9. The mutual activities (EMIT- Elcam) required to approve this material change should be managed and coordinated by both teams at EMIT and Elcam and must be completed by June 2025.

2. Objectives

2.1. Design Verification & Validation (Design V&V) on real time aging - Product performance testing compared to Product Requirements Document (PRD) and Marketing Requirements Document (MRD).

3. References

	Description	Doc ID	Revision
3.1.	MRD - Marketing Requirements Document	N.A.	-
3.2.	PRD - Product Requirements Document	Doc-310149	B
3.3.	Product risk management document (Product's FMEA)	Doc-310418	C
3.4.	Design Verification Report Document	Doc-331335	A
3.5.	ACT-0677-AAMI ISO CN27-2021- Design Verification & Validation Report	Doc-299806	A
3.6.	Test Protocol - Microbial Ingress Test 11 days multiple activations and prolonged connection	Doc-330808	A
3.7.	Other		

4. Guiding Considerations

4.1. The product's critical properties following sterilization of Gamma 40 kGy + 2 cycles of EtO were:

4.1.1. Leakage resistance to air and liquids.

4.1.2. Leakage resistance after prolonged connection.

4.1.3. Leakage resistance after multiples activations.

Following the change in the septum material, the NIP Stand-Alone product will be tested according to standard AAMI ISO CN27-2021, for all tests related to the septum. Additional tests from the AAMI ISO CN27-2021 standard related to the Luer connectivity according to 80369-7 were not included in this document because no change was made to the Luer connection. Tests related to connectivity were accomplished in previous projects RPJ-501 & PRJ-0567 & PRJ-0577.

4.2. Guiding considerations for tests selection:

4.2.1. This stability plan will focus only on tests that may be affected by natural aging over time. Since accelerated aging creates more severe conditions due to the elevated temperature (52°C) and humidity in the oven. Therefore, we will exclude all tests that are not time-dependent, as follows:

4.2.1.1. Dimensions report.

4.2.1.2. Particulate contamination test.

4.2.1.3. Verification of flow rate.

4.2.1.4. Test for priming volume.

4.2.1.5. Test for residual volume.

4.2.1.6. Test for Displacement.

4.2.1.7. Microbial ingress- Swabability and microbial barrier

4.3. Guiding considerations for time intervals selection:

4.3.1. Time intervals were selected for 3 and 5 years. Stability Tests for time zero was already successfully tested during the design verification. According to clients requirement final shelf life should be five years.

4.4. **Sample Sizes setting** (by statistical rational):

4.5. Sample size setting default is: According to Elcam's procedure 3-01-45 (ISO16269-6:2005): According to the standard, at confidence level of 95% for a one sided or pass/fail acceptance a Critical performance (graded as Red risk on Risk Analysis) requires minimum 299 parts, a Major performance (graded as Yellow risk on Risk Analysis) requires minimum 59 parts per test and a Minor performance (graded as Greened risk on Risk Analysis) require minimum 29 parts. Where risk level is set on project risk analysis.

4.6. **Sterilizations Required:**

4.6.1. As approved in the V&V report products The required sterilization is: Gamma 40 kGy Min., followed by 2 EtO cycles.

4.6.2. Each group will be packed inside two test boxes PN 130162, size 20x20x20 cm containing 650 products each, and one dosimeter will be placed inside each box for each irradiation cycle. This test box is according to SOP 4-01-20, where one dosimeter is located in the box center, its reading represents ±5% volume dissipation.

4.7. **Other Preliminary Treatments** – N.R.

4.8. **Transportation Simulation**: No geometrical design modification was performed in this project. Therefore, we will rely on Validation for shipping made to similar products, see Doc-157254: Elcam Products Performance after shipping - NIP stand-alone -Test Summary, Val-1514-Elcam Products Performance after shipping.

4.9. **Products sold in a sterile packaging** (blisters), require Sterilization Validation process for the sterility – according to Regulation department procedures- N.R.

4.10. Indicate which products are represented in this test, specify which properties they represented:

Description	Illustration	P. N	Representing	Properties and justification for selection
New Stand-Alone		220808L	All LAV products with similar septum and cap.	New product with new septum PN 590422. The design and production of the LAV products are all similar. The properties that perform the sealing and the connection are similar.

5. Testing Preparations

5.1. Preliminary Treatments: N.R.

5.2. Sterilization: Gamma irradiation 40 kGy Min. followed by two EtO cycles.

5.3. Transportation and storage Simulation: N.R.

5.4. More:

5.5. Groups Identification Table:

Group #	PN	Product description	LOT #	Required Sterilization	Required Aging- years	Planned Test date (MM/YY)	Quantity for production	Packaging instruction
1	220808 L	NIP STAND-ALONE	TBD	40 kGy Gamma +2 EtO cycles	3 yrs	TBD	1300	See 4.6.2 and after preliminary treatment in BNS.
2	220808 L	NIP STAND-ALONE	TBD	40 kGy Gamma +2 EtO cycles	5 yrs	TBD	1300	

5.6. Parts and products versions to be tested:

Component/Product Name	Identification	Part Number	Version	Lot Number
NIP split Septum	Component	590422	0	TBD
Nip cap	Component	530145	B	TBD
NIP Stand-Alone	Product	220808L	0	TBD

5.7. Test Details and sample sizes:

Product Name		Group#		Total
Test para#	Test Name	1	2	
6.1	Visual inspection	30	30	60
6.2	Verification test to confirm that the slit remains open	300	300	600
6.3	Positive pressure liquid leakage- Activated state.	30	30	60
6.4	Subatmospheric pressure air leakage – Unactivated and Activated state.	30	30	60
6.5	Air Leakage test According to ISO 8536-4	30	30	60
6.6	Hydraulic high pressure burst test	30	30	60
6.7	Number of activations	30	30	60
6.8	Test for back pressure -unactivated	30	30	60
6.9	Test for exposure to IPA.	30	30	60
6.10	Duration of activation unactivated-state	30	30	60
6.11	duration of activation+ Infusate compatibility activated-state	30	30	60
6.12	Gauge insertion force	30	30	60
6.13	Tensile force test as per ISO 8536-4	30	30	60
6.14	Product NIP US welding strength test	30	30	60
6.15	Lipid Resistance of Female Connector	30	30	60
Total:		720	720	1440

6. Test Details

6.1. Test Name: Visual inspection of the NIP Stand-Alone valve and septum component.

Responsibility	Elcam's Laboratory.
Purpose:	Test whether the Stand-Alone valve and septum have visual defects.
Test Applicability:	Test whether the Stand-Alone valve and septum have no visual defects that might damage their performance.

Risk Addressed by test:	The product doesn't meet visual requirements that can cause damage to the function and safety of the product.
Tested Device:	According to table on section #5.5
Equipment:	MANTISx4- Visual Inspection Microscope
Treatments:	According to table on section #5.5
Test Method (protocol):	According to Elcam's procedure 3-06-03, Appendix 5, Rev.34. During the test, the NIP Stand-Alone valve and septum are inspected for visual failures that are deviated from product's specification. The inspector uses optical tool (Mantis -Visual Inspection Microscope) to detect deviations in shape, imperfections and the surface condition on the product's surface. Defects that required to be noted in the visual inspe2ction are: Hits, discolored, external flashes, cracks, embedded particles, debris, hits. Furthermore, Insert Luer lock syringe to the septum and check by operating the piston that the slit is open (air can pass).
Sample size:	According to table on section #5.7
Acceptance criteria:	None of the findings will damage the function and safety of the product, and the slit in the septum is open after one activation.
Results:	*At Test Report stage: specify the tests' results.* *For quantitative results you may use the following table to present results.* Min Max AVG (mean) STD
Discussion and Conclusion:	*At Test Report stage: Provide a short discussion about the tests results vs. acceptance criteria and whether the product met the test's acceptance criteria.*

6.2. Test Name: Verification test to confirm that the slit remains open at Activated state with Luer slip.

Responsibility	Elcam's Laboratory
Purpose:	Verification test to ensure the slit does not reseal and remains open over time when a Luer slip connector is connected.
Test Applicability:	A visual usability test to verify that the slit remains open and does not close after Gamma and EtO sterilization and prolonged aging, which could compromise the product's usability.
Risk Addressed by test:	The product cannot be used after Gamma and EtO sterilization and prolonged aging
Tested Device:	According to table on section #5.5
Equipment:	Syringe with Luer slip
Treatments:	According to table on section #5.5
Test Method (protocol):	1. Connect the syringe with the male Luer slip to the female NIP septum connection. 2. Pull back the piston to draw air through the device. 3. If the piston stays retracted, the slit is open; if it springs back, a vacuum has formed, indicating the slit is closed. 4. When the piston stays retracted, visually inspect the slit to ensure it is fully open along its entire length.
Sample size:	According to table on section #5.7
Acceptance criteria:	The entire slit remains open and unobstructed, allowing fluid to pass freely.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.3. Test Name: Positive pressure liquid leakage- Activated state.

Responsibility	Elcam's Laboratory
Purpose:	Verifying withstanding liquid leak under pressure of 330 KPa for 35 sec. when connected to a male reference connector.
Test Applicability:	To confirm that the product does not leak while connected to a male reference connector. The test is based on AAMI ISO CN27-2021 Sec. 5.8 and ISO 80369-7 annex B, and conducted according to Elcam's SOP no. 4-02-67 Rev.2 section 6.9: test at 330 KPa during 35 sec.
Risk Addressed by test:	Not meeting AAMI ISO CN27-2021spec, Sec. 5.8.
Tested Device:	According to table on section #5.5
Equipment:	Barometer Stopwatch Air pressure source line Water with colorant
Treatments:	According to table on section #5.5
Test Method (protocol):	According to Elcam's SOP 4-02-67 Rev.1 sec 6.9. Perform 140 activations with Luer slip syringe for all tested products in the groups. Connect a Monoblock to IV tube. Connect the tested products to the Monoblock. Connect a male reference to the LAV port- for activated state. Fill the system with colored water. Increase the pressure in the system by filling air pressure of 330 KPa for 35 sec.
Sample size:	According to table on section #5.7
Acceptance criteria:	According to Elcam procedure 4-02-67, there shall be no leakage of water during 35 sec.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.4. Test Name: Sub atmospheric pressure air leakage – unactivated and Activated state.

Responsibility	Elcam's Laboratory
Purpose:	To withstand subatmospheric (vacuum) pressure air leakage according to AAMI ISO CN27-2021. For **unactivated** LAV sec.5.9. For **activated** LAV sec.5.10.
Test Applicability:	Subatmospheric (Vacuum) pressure air leakage test according to AAMI ISO CN27-2021 sec. 5.9 and 5.10 in unactivated and activated state.
Risk Addressed by test:	Not meeting AAMI ISO CN27-2021 sec. 5.9 and 5.10. requirements.
Tested Device:	According to table on section #5.5
Equipment:	Vacuum pump with a vacuum gauge. Rigid tube.
Treatments:	According to table on section #5.5
Test Method (protocol):	First, conduct the test on the Stand-Alone products while the LAV are in an unactivated state. Then, perform the test on those same products while the activated state is applied. The Stand-Alone product should be connected to the vacuum source on the side of the MLLC connection (the side without the valve). Perform 140 activations with Luer slip syringe for all tested products in the groups. **Unactivated**: According to Elcam's procedure 4-02-67 Rev.1, section 6.10 Connect the LAV to a vacuum device. Apply vacuum with an internal negative pressure of 20 kPa to the infusion set during 15 sec. Atmospheric pressure shall be the reference

	pressure. Inspect if air enters into the products. **Activated:** According to Elcam's procedure 4-02-67 Rev.2, section 6.11. Connect the LAV to a vacuum device when connected to a male reference connector and close all remaining openings. Apply vacuum with an internal negative pressure of 88 kPa to the infusion set during 15 sec., Atmospheric pressure shall be the reference pressure. Inspect if air enters into the products.
Sample size:	According to table on section #5.7
Acceptance criteria:	For unactivated and activated state: - The vacuum drop should not exceed 1 kPa (0.01 bar). - There should be no entry of air bubbles into the liquid passage for 15 seconds. - There should be no movement of any existing air bubbles for 15 seconds.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.5. Test Name: Air Leakage test according to ISO 8536-4

Responsibility	Elcam's Laboratory
Purpose:	Verifying withstanding air leak under pressure according to ISO 8536-4 Sec. A.3.2.
Test Applicability:	To confirm that the product meets the air leakage requirements of ISO 8536-4 Sec. A.3.2.
Risk Addressed by test:	Not meeting leakage of air pressure, according to ISO 8536-4.
Tested Device:	According to table on section #5.5
Equipment:	☐ Barometer ☐ Air pressure source line ☐ IV set ☐ Stopwatch
Treatments:	According to table on section #5.5
Test Method (protocol):	According to procedure 4-02-37, Rev. 4, clause 6.4.3 Connect the product to a compressed air supply using a male or female connector in accordance with ISO 80369-7. Apply air with an internal excess pressure of 0.5 bar during 15 sec. Immerse the product under water at 40 ± 1 °C and inspect for any leakage of air.
Sample size:	According to table on section #5.7
Acceptance criteria:	Products should not leak at a pressure of 0.5 bar for 15 sec., under water temperature at 40°C.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.6. Test Name: Hydraulic high pressure burst test.

Responsibility	Elcam's Laboratory
Purpose:	To verify that the product meets the liquid leakage requirement.
Test Applicability:	To confirm that the product meets the liquid leakage requirements.
Risk Addressed by test:	The product will not meet the liquid leakage spec.
Tested Device:	According to table on section #5.5
Equipment:	HBLT Model 2000 made by Crescent, distilled water.
Treatments:	According to table on section #5.5
Test Method	According to Elcam's SOP 4-02-45 Rev. 5, program: HR Valve Burst.

(protocol):	Connect the Stand-Alone LAV to the outlet female of the HBLT device. Activate the LAV with a male reference connector, in order to drain the air. Run HBLT program in **unactivated state**- HR Valve Burst. Record the final pressure burst results, and the area of leakage if any.
Sample size:	According to table on section #5.7
Acceptance criteria:	According to Elcam procedure 4-02-45 Rev. 5, there shall be no leakage of water below pressure of 30 PSI.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.7. Test Name: Number of activations. See section 4.17.1.

Responsibility	Elcam's Laboratory
Purpose:	The LAV shall be resistant to liquid pressure, 2 bar for 15 min at 40 °C, after multiple insertions and disconnections of: male Luer lock >140 times or male Luer slip >140 times.
Test Applicability:	To ensure LAV meet product performances after multiple insertions and disconnections, according to the test method according to ANSI/AAMI CN27 and Elcam spec 4-02-67 sec 6.1.
Risk Addressed by test:	Not meeting ISO CN27 sec.5.12 spec.
Tested Device:	According to table on section #5.5
Equipment:	Infusion set, Air compressor, barometer, colored water, LLOYD measurement machine.
Treatments:	According to table on section #5.5
Test Method (protocol):	- Activate the LAV with **Male Luer slip** - 140 times, of cycles according to procedure 4-03-10. - Activate the LAV with **Male Luer lock** - 140 times, of cycles according to procedure 4-03-10. After the cycles: - Perform a visual inspection of the valve according to procedure 4-03-10. - Document the results in Appendix 1 of instruction 4-03-10. - Perform a liquid pressure test of 2 bar over 15 minutes at 40°C according to procedure 4-02-37 sec.6.4.4.
Sample size:	According to table on section #5.7
Acceptance criteria:	there shall be no leakage of water at 2 bar over 15 minute at 40°C.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.8. Test Name: Test for back pressure -unactivated

Responsibility	Elcam's Laboratory
Purpose:	To ensure LAV in the unactivated state withstand a back pressure of 2 bar and 0.5 bar during 35 sec.
Test Applicability:	The LAV in the unactivated state shall withstand a back pressure of 2 bar and 0.5 bar during 35 sec.
Risk Addressed by test:	Not meeting spec ISO CN27 sec.5.7.
Tested Device:	According to table on section #5.5

Equipment:	Colored water, air pressure source.
Treatments:	According to table on section #5.5
Test Method (protocol):	Testing according to Elcam SOP 4-02-67 sec 6.8. Perform 140 activations with Luer slip syringe for all tested products in the groups. Apply the high and low pressures when the LAV is in unactivated state.
Sample size:	According to table on section #5.7
Acceptance criteria:	The LAV shall show no signs of leakage over the hold period consistent with the high and low pressures.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.9. Test Name: Test for exposure to IPA.

Responsibility	Elcam's Laboratory
Purpose:	compatibility with 70 % Isopropyl alcohol (IPA).
Test Applicability:	To consider the relative use environment and assess the risks associated with the use of IPA according to the test method according to ISO CN27 sec. 5.2.
Risk Addressed by test:	Not meeting ISO CN27 spec sec. 5.2.
Tested Device:	According to table on section #5.5
Equipment:	IPA, Air compressor, barometer, colored water.
Treatments:	According to table on section #5.5
Test Method (protocol):	Test method according to Elcam SOP 4-02-67 sec.6.3. 1. Expose the LAV to IPA by wiping the valve. While it is wet connect it to an ISO 80369-7 compliant Luer connector (Fig C.4) according to the procedure 4-03-22. 2. Leave it connected for one hour. 3. Visual check of product. 4. Check leakage test according to procedure 4-02-20.
Sample size:	According to table on section #5.7
Acceptance criteria:	Not one drop may be released during 35 sec. in 0.5 and 2 bar.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.10. Test Name: Duration of activation unactivated-state.

Responsibility	Elcam's Laboratory
Purpose:	The LAV shall close and seal after being in an unactivated state for the longest intended use period claimed: 11 days (264 hours) at 0.2 bar, then 15 min at 2 bars.
Test Applicability:	Not meeting AAMI ISO CN27-2021 Spec.
Risk Addressed by test:	Not meeting product optional usage life of 11 days (264 hours) Max.
Tested Device:	According to table on section #5.5
Equipment:	☐ Barometer ☐ Stopwatch ☐ Air pressure source line ☐ Water with red colorant
Treatments:	According to table on section #5.5
Test Method (protocol):	Connect the LAV products for testing according to procedure 4-02-20, Rev. 6. Connect the products to a liquid pressure of 0.2 bar for 11 days (264 hours). Check for leaks and document them once every 24 hours. Furthermore, every 24 hours, perform a liquid

	pressure resistance test at 2 bar for 15 minutes, and then reduce the pressure back to 0.2 bar.
Sample size:	According to table on section #5.7
Acceptance criteria:	According to Elcam procedure 4-02-20, there shall be no leakage of water during all test period.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.11. Test Name: duration of activation+ Infusate compatibility.

Responsibility	Elcam's Laboratory
Purpose:	Infusate compatibility for longest duration of use 11 days (264 hours). The LAV shall close and seal after being in an activated state for the longest intended use period claimed: 11 days (264 hours) at 0.2 bar, then 15 min at 2 bars.
Test Applicability:	To consider the relative use environment and assess the risks associated with the use of infusate according to AAMI ISO CN27-2021 sec.5.3 and 5.11.
Risk Addressed by test:	Not meeting ISO CN27 spec. Not meeting product optional usage life of 11 days (264 hours) Max.
Tested Device:	According to table on section #5.5
Equipment:	Infusion set, Air pressure source line, barometer, Stopwatch, colored water.
Treatments:	According to table on section #5.5
Test Method (protocol):	Test method according to Elcam SOP 4-02-67 sec.6.2. 1. Expose the LAV to the selected test conditions (connecting it to infusion 1m high with colored water), connecting it to an ISO 80369-7 compliant Luer connector (Fig C.4) according to the procedure 4-03-22. 2. Leave it connected for 264 hours. Leak testing and documentation will be performed every 24 hours. On 7th day (168 hours) and 11th day (264 hours), disconnect the Male Luer Connector and perform a liquid pressure resistance test at a pressure of 2 bar for 15 minutes, and then reduce the pressure back to 0.2 bar. Reconnect the Male Luer Connector to continue the test.
Sample size:	According to table on section #5.7
Acceptance criteria:	Not one drop may be released during all test period of 11 days at pressure of 0.2 and 2 bar.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.12. Test Name: Gauge activation/ insertion force.

Responsibility	Elcam's Laboratory
Purpose:	To check the required force to activate/open the valve.
Test Applicability:	To compare the force required to activate the new valve comparing to the current valve.
Risk Addressed by test:	Not meeting ISO CN27 spec.
Tested Device:	According to table on section #5.5
Equipment:	LLOYD machine, gauge LA001114265
Treatments:	According to table on section #5.5
Test Method (protocol):	Test method according to Elcam SOP 4-02-50. Insert the product to gauge LA001114265, with valve facing up. Lower the tip of the metal gauge as close to the face of the valve as possible (zeroing state), making sure the gauge is centered in relation to the valve so that the gauge can

	penetrate the valve. Start the force measurement test. The gauge should enter 8 mm deep from zeroing state.
Sample size:	According to table on section #5.7
Acceptance criteria:	Activation force AVG X ≤ 30 N Load At Max. insertion.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.13. Test Name: Tensile force test as per ISO 8536-4 Sec. 7.3

Responsibility	Elcam's Laboratory
Purpose:	To verify that the connections between components shall withstand a static tensile force of not less than 15N for 15sec. acc. to ISO 8536-4 Sec. 7.3.
Test Applicability:	To verify that the connections between components shall withstand a static tensile force of not less than 15N for 15sec. acc. to ISO 8536-4 :2019 Sec. 7.3.
Risk Addressed by test:	Not meeting ISO 8536-4 Sec. 7.3 requirements.
Tested Device:	According to table on section #5.5
Equipment:	Lloyd Testing Machine
Treatments:	According to table on section #5.5
Test Method (protocol):	According to Elcam's SOP 4-02-37 Rev. 2 section 6.3.3 Expose the product to be tested in longitudinal direction to a static tensile force of 15 N for 15 sec. Expose the cap to the same force in the direction of the rotational axis of its plug. Inspect whether points of connection and components withstand the test force applied
Sample size:	According to table on section #5.7
Acceptance criteria:	Components withstand a static tensile force of 15 N for 15 sec.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.14. Test Name: Product NIP **U**ltra-**S**onic (named US) welding strength test.

Responsibility	Elcam's Laboratory.
Purpose:	Verify the strength of the US welding between the cap to the MLLC base.
Test Applicability:	Verifying the strength of the US welding between the cap to the MLLC base using a torque meter.
Risk Addressed by test:	Risk of the US welding between the cap to the MLLC base, will brock during use.
Tested Device:	According to table on section #5.5
Equipment:	Torque meter S.N. 221415 Adaptor device LA031280207
Treatments:	According to table on section #5.5
Test Method (protocol):	According to Elcam SOP 4-02-53 (Rev 8) clause 6.2.
Sample size:	According to table on section #5.7

Acceptance criteria:	According to Elcam SOP 4-02-53 (Rev 8) clause 6.3. The product is approved, if bending forces up to 140 In•Oz in horizontal direction and 100 In•Oz in vertical direction, did not deform or break the US connection.
Results:	*TBD*
Discussion and Conclusion:	*TBD*

6.15. Test Name: Lipid Resistance of Female Connector (530145-NIP CAP) according to B. Braun procedure.

Responsibility	Elcam's Laboratory
Purpose:	To test the lipid exposure resistance level of the Female Connector in the product.
Test Applicability:	To ensure lipid resistance during product usage life of 11 days (264 hours) Max. according to Elcam Spec. 0090-G Rev-D.
Risk Addressed by test:	Not meeting ISO CN27 spec. Not meeting product optional usage life of 11 days (264 hours) Max.
Tested Device:	According to table on section #5.5
Equipment:	Infusion set, Air pressure source line, barometer, Stopwatch, colored water.
Treatments:	According to table on section #5.5
Test Method (protocol):	Test method according to Elcam SOP 4-03-80 edition 5 sec.6.2. Cracking and leakage tests in lipid. The test should be performed every 24 hours for up to 12 days (5 disconnections and reconnections per day).
Sample size:	According to table on section #5.7
Acceptance criteria:	No leakage or breakage that could lead to leakage, after lipid exposure for more than 48 hours and up to 288 hours (2 days to 12 days).
Results:	*TBD*
Discussion and Conclusion:	*TBD*

7. Revision Tracking

Revision Number	Revision date	Change description	Changed by
A	15-May-2025	First version	Israel L.

8. Approvals

Position	Name	Date	Signature
Product Engineer	-	-	-
R&D Manager / CTO	-	-	-
QA Engineer	-	-	-

-End of Document-