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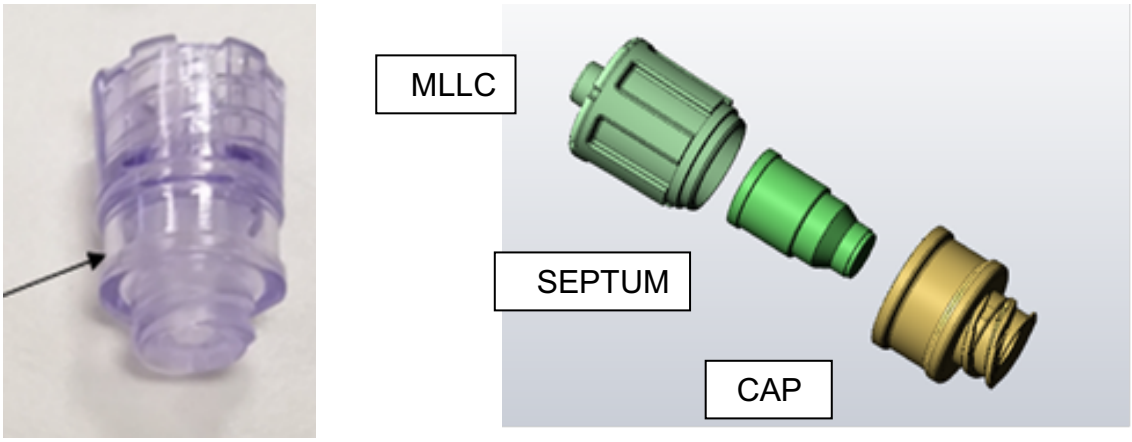
1. Summary

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) - Product performance testing compared to Product Requirements Document (PRD) and requirements according to AAMI ISO CN27-2021 General spec G-0090 requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications.

3. References

State Document number (DOC ID#) or Document title and Revision.

	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 V&V plan	Doc-3313350	A
3.5.	PRJ-0501-Haemopharm NIP-Design V&V Report	Doc-088691	B
3.6.	PRJ-0567-Improved cap for LAV -Design Verification & Validation Report	Doc-115698	C
3.7.	PRJ-0577-Stand Alone NIP-Design Verification & Validation Report	Doc-131742	F
3.8.	ACT-0677-AAMI ISO CN27-2021- Design Verification & Validation Report	Doc-299806	A
3.9.	Elcam Products Performance after shipping - NIP stand-alone -Test Summary. Val-1514-Elcam Products Performance after shipping.	Doc-157254	A
3.10.	ECO-24-0005-PN 590408 - Silicone Change	Doc-301367	01
3.11.	PRJ 0695-Silicon Change on NIP valve -Regulatory Review	Doc-311581	A
3.12.	Test Protocol - Microbial Ingress Test 11 days multiple activations and prolonged connection	Doc-330808	A
3.13.	1.10 Form, manufacturing documents and laboratory results	Doc-332798	-
3.14.	Laboratory Test results report	Doc-332799	-
3.15.	Aging report	Doc-332102	A
3.16.	Dimensional report	Doc-332096 Doc-332095	A A
3.17.	Gamma Sterilization report	Doc-332122	A
3.18.	ETO Sterilization report	Doc-332113	A
3.19.	PRJ-0695-Silicon Change on NIP valve-Product Stability Test Protocol	Doc-332257	A
3.20.	PRJ-0695-Silicon Change on NIP valve-Design Verification & Validation Plan	310150	B

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.

4.2. Following the change in the septum material, the NIP Stand-Alone product was 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 verification report because no change was made to the Luer connection. Tests related to connectivity were accomplished in previous projects RPJ-501 & PRJ-0567 & PRJ-0577.

4.3. Furthermore, the production of the Stand-Alone product using ultrasonic welding has also been transferred to EMIT, so we also didn't conducted tests related to the strength of the product's welding.

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

4.4.1. 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.

4.4.2. Sample size for quantitative measurement such as dimensions measurements was calculated with JMP13 based on measurements taken from PRJ-0552-ISO-80369-7. The parameters that we used in the software calculation were:

4.4.2.1. α=5%; Power=95%;

4.4.2.2. Difference to Detect (DTD) = 0.01 *[mm];*

4.4.2.3. Std dev error = 0.000049 (measured for N=30) according to preliminary results.

4.4.2.4. Required sample size=> 4 units.

4.4.3. Samples sizes of this plan were set according to SOP# 3-01-45 and Risk Analysis -see sample size details on section 6.7

4.5. **Sterilizations Required:**

4.5.1. The default for sterilization was: Gamma 25 kGy followed by 2 ETO cycles.

4.5.2. New Groups (F2 & F3 & F5 and D2 & D3) were sterilized: Gamma 40 kGy followed by 2 ETO cycles. See section #6.2.4 for actual Gamma reading.

4.5.3. Additional groups were submitted only to 2 ETO cycles sterilization, as backup groups in case the Gamma sterilized groups fail the tests.

4.5.4. Each group was packed inside test box PN 130162, size 20x20x20 cm containing 650 products each, and one dosimeter was 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.

4.6. **Other Preliminary Treatments** –NR.

4.7. **Shelf life-Accelerated Aging** (according to SOP# 3-01-39):

According to SOP# 3-01-39, based on spec. ASTM F 1980 Rev 21.

4.7.1. Accelerated aging method is based on chemical reactions expressed at by the Arrhenius reaction rate function. The duration in the ovens is calculated based on the Arrhenius model, when: Q10=2.0; TRoom=23ºC; TTest=52 ºC where 50 days in the oven simulates one year of real time aging.

4.7.2. The assembled products were divided to different groups of accelerated aging to simulate real environmental conditions and natural aging of shelf-life, that is equivalent to one month, three and five years. Aging procedure were conducted at two aging temperatures of 52°C and 60°C. The groups of accelerated aging using TTest=60 ºC (29 days in the oven simulates 1 year of real time aging) were chosen in order to get the fastest results. The aging groups at 52°C were backup groups, and were added to the project since we have previous experience, that accelerating aging at 60°C can damage the tested products and are sometimes worse than results compared to natural aging. The followed aging groups at 52°C were backup groups: A2, A3, B2, B3, C2, F3. these groups were not tested because groups of accelerated aging of 60°C passed all tests successfully.

4.7.3. Specify planned aging conditions for this test:

Equivalent aging	**Oven temp (°C)**	**Duration in oven** (days)	**Relative humidity %**
~1 month (52 days)	52°C	7 days	50% ±5%
2 years	52°C	98 days	50% ±5%
5 years	52°C	245 days	50% ±5%
2 years	60°C	57 days	50% ±5%
5 years	60°C	141 days	50% ±5%

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 clause 3.9.

4.9. **Storage Simulation-real time aging:**

4.9.1. Storage simulation-real time aging was done according to the stability test protocol Doc-332257.

4.9.2. The real-aging timeframes is 2 and 5 years, similarly to the accelerated aging.

4.10. Products **sold in a sterile packaging** (blisters): NR.

4.11. Indicate which products are represented in this project, specify which properties they represented:

Description	Illustration	P. N	Representing	Properties and justification for selection
Current Stand-Alone		220808	All LAV products with similar septum and cap.	Current product with septum PN 590408 for comparison.
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.

4.12. Required information to be documented and refer to, when relevant:

4.13. Previews engineering tests- According to primary tests, new Stand-alone products with new septum PN 590422 were exposed to Gamma Irradiation at 40 kGy, and 80 activations Luer slip, then visually inspected and tested to leakage at 2 bar. Tests passed successfully.

4.14. The following tests are not time dependent and will not change over aging time; therefore, they were tested only on one group from each different treatment option (one week or two years) and accelerated aging:

4.14.1. Particulate contamination test.

4.14.2. Verification of flow rate.

4.14.3. Test for priming volume.

4.14.4. Test for residual volume.

4.14.5. Test for Displacement.

4.15. **Biocompatibility tests**, including raw materials details and detailed components which are in contact with patients or user – will be performed according to ISO 10993, under 'blood contact, indirect, prolonged duration, see clause 3.11.

4.16. **Microbial ingress** (Swabability and microbial barrier) according to ANSI/AAMI CN27 Sec. 5.17.
The device should function as a microbial barrier and should have swabbable surface so that it will be possible and easy to clean during medical procedures.
This test was conducted on products from group F5, by external laboratory and supervisory by Elcam QA department, see clause 7.20.

4.17. **Non interconnectability according to ISO 80369-7**. Functional tests and measurement to confirm ISO 80369-7 compliance was already performed and approved in RPJ-501 & PRJ-0567 & PRJ-0577.

4.18. **Changes from the Design V&V Plan:**

4.18.1. Due to expansion of activity in the project's content, it was decided to change the activity from ACT (activity) to PRJ (project).

4.18.2. Following a new request from the Sales department, it has been decided to modify the number of activations tests and the method of activation, Luer slip or Luer lock, appearing in the number of activations requirements. The number of activations was changed to: Male Luer lock => 140 times; Male Luer slip => 140 times. (Previously: Male Luer lock => 120 times, Male Luer slip => 170 times). Test section 7.9- Number of activations, was modified to support this request.

4.18.3. Three new test groups (F2 & F3 & F5) and two groups (D3 & D4) have been added to the test plan to meet a customer requirement, for product approval after exposure to 40 kGy gamma radiation. These groups are spares products from Group A (previously ETO sterilized) and have undergone 40 kGy irradiation at Sovan after accelerated aging. The new groups include products aged for 2 and 5 years at 52°C and 60°C, were added and specified in Table 6.4.

4.18.4. The CSTP (**C**lose **stop**cock) PN 581993 has been added to the project scope, due to the replacement of the silicon valve PN: 590408, as described above. Based on our risk assessment, retesting of the CSTP is unnecessary as all other components except the valve remain unchanged. The sealing area and ultrasonic welding design are identical in both products. Additionally, both products are assembled on the same assembly line (CW709) using the same manufacture parameters. Therefore, approval of the Stand-alone product extends also to the CSTP. See ECO-04-005.

4.18.5. In visual inspection, section # 7.1 we have added a requirement to verify also that the slit is open after a single activation and allows flow.

4.18.6. The test plan was designed with several identical product groups, each subjected to different accelerated aging and sterilization conditions. The objective is to approve the group that underwent the most severe sterilization of 40 kGy, with accelerated aging of 5 years at 60°C=> Group F. To minimize unnecessary testing, it was decided to focus on testing Group F5-5-60-EG, and if all tests are successful, we can proceed with approval based on this group without testing the remaining groups. Therefore, we are presenting only the test results of Group F5-5-60-EG compared to Control Group C4-5-60-ET. All other groups result were not fully tested, but group that were tested, passed successfully and were saved in the project file.

5. Design Validation

Guiding Considerations for Design Validation:

5.1. Design Validation ensures that the device conforms to user needs and intended use.

5.2. At this project no Design Validation is needed since we didn't make any design changes in the product, only the septum material was replaced.

6. Testing Preparations

6.1. Preliminary Treatments: N.R.

6.2. Sterilization:

6.2.1. Option I: Two ETO cycles.

6.2.2. Option II: Gamma irradiation 25 kGy Min. followed by two ETO cycles.

6.2.3. Option III: Gamma irradiation 40 kGy Min. followed by two ETO cycles.

6.2.4. **Actual dosimeters reading** *(from Sorvan Report)*: see reports referenced in sections 3.17.

Groups	EtO	Required Gamma Irradiation Min / Max. [kGy]	Total Dosimeters readings [kGy]	Minimum actual [kGy] (-5%)*	Maximum actual [kGy] (+5%)*
C5	2 cycles	N.R.	N.R.	-	-
F5	2 cycles	40 / 46	45.11	42.85	47.36
D4	2 cycles	40 / 46	46.66	44.33	48.99

*See section 4.5.4

6.3. Transportation and Storage Simulation: N.R.

6.4. Groups Identification Table:

Assemblies:							
Group #	**PN**	**Product description**	**LOT #**	**Sterilization details**	**Aging details**	**Quantity for production**	**Packaging instruction and notes**
A1-1W-52-ET	220808L	NIP STAND-ALONE	2403251640	2 EtO cycles	~1 month (52 days) = 7 days@52°C	4000 Units	BNS Groups sterilized only ETO.

A2-2-52-ET				2 EtO cycles	2 years = 98 days@52°C		Assembled with Septum PN590422
A3-5-52-ET				2 EtO cycles	5 years = 245 days@52°C		
A4-2-60-ET				2 EtO cycles	2 years = 57 days@60°C		
A5-5-60-ET				2 EtO cycles	5 years = 141 days@60°C		
B1-1W-52-EG	220808L	NIP STAND-ALONE	2403251640	25 kGy Gamma +2 EtO cycles	~1 month (52 days) = 7 days@52°C	4000 Units	BNS Groups sterilized Gamma+ ETO. Assembled with Septum PN590422
B2-2-52- EG				25 kGy Gamma +2 EtO cycles	2 years = 98 days@52°C		
B3-5-52-EG				25 kGy Gamma +2 EtO cycles	5 years = 245 days@52°C		
B4-2-60-EG				25 kGy Gamma +2 EtO cycles	2 years = 57 days@60°C		
B5-5-60-EG				25 kGy Gamma +2 EtO cycles	5 years = 141 days@60°C		
C1-2-52-ET	220808	NIP STAND-ALONE	2402130846	2 EtO cycles	2 years = 98 days@52°C	4000 Units	BNS Current product. Only for comparison. Assembled with Septum PN590408
C2-5-52-ET			2402130846	2 EtO cycles	5 years = 245 days@52		
C3-2-60-ET			2402130846	2 EtO cycles	2 years = 57 days@60°C		
C4-5-60-ET			2402130846	2 EtO cycles	5 years = 141 days@60°C		
F2-2-52- EG	220808L	NIP STAND-ALONE	2403251640	40 kGy Gamma +2 EtO cycles	2 years = 98 days@52°C	1500 Units	BNS Groups sterilized Gamma+ ETO. Assembled with Septum PN590422
F3-5-52-EG				40 kGy Gamma +2 EtO cycles	5 years = 245 days@52°C		
F5-5-60-EG				40 kGy Gamma +2 EtO cycles	5 years = 141 days@60°C		
D1-5-52-ET	220808L	NIP STAND-ALONE	2403251640 -1	2 EtO cycles	5 years = 245 days@52°C	250 Units	Packed in Blister For test 4.16
D2-5-60- ET			2403251640 -2	2 EtO cycles	5 years = 141 days@60°C	250 Units	
D3-5-52-EG	220808L	NIP STAND-ALONE	2403251640 -1	40 kGy Gamma +2 EtO cycles	5 years = 245 days@52°C	250 Units	Packed in Blister For test 4.16
D4-5-60- EG			2403251640 -2	40 kGy Gamma +2 EtO cycles	5 years = 141 days@60°C	250 Units	
E1-5-52-EG	220808L	NIP STAND-ALONE	2403251640 -1	25 kGy Gamma +2 EtO cycles	5 years = 245 days@52°C	1000 Units	Packed in Blister For test 4.16
E2-5-60-EG			2403251640 -2	25 kGy Gamma +2 EtO cycles	5 years = 141 days@60°C		

6.5. Components and products related to design verification:

Part numbers components\ products
590422
220810
220808
590408

6.6. Parts and products versions that were tested:

Component/Product Name	Identification	Part Number	Version	Lot Number
NIP split Septum	Component	590422	0	2410001443
Nip cap	Component	530145	B	2313578901
NIP Stand-Alone MLLC	Component	210810L	A	2307254643
NIP Stand-Alone	Product	220808L	0	2403251640

6.7. Test Details and Sample Sizes:

Product Name		Group#																Total
Test para #	Test Name	A1-1W-52-ET	A2-2-52-ET	A3-5-52-ET	A4-2-60-ET	A5-5-60-ET	B1-1W-52-EG	B2-2-52- EG	B3-5-52-EG	B4-2-60-EG	B5-5-60-EG	C1-2-52-ET	C2-5-52-ET	C3-2-60-ET	C4-5-60-ET	F2-2-52- EG	F3-5-52-EG	F5-5-60-EG	
7.1	Visual inspection	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510
7.2	Measurements	4	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-	-	8
7.3	Particulate test acc. USP 788 Particles in Injec.	30	-	-	-	-	30	-	-	-	-	30	-	-	-	30	-	-	120
7.4	Positive pressure liquid leakage- Activated state.	60	60	60	60	60	60	60	60	60	60	30	30	30	30	60	60	60	900
7.5	Subatmospheric pressure air leakage – Unactivated and Activated state.	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510
7.6	Air Leakage test	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510

Product Name		Group#																Total
	According to ISO 8536-4																	
7.7	Hydraulic high pressure burst test	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510
7.8	Verification of flow rate	30	-	-	-	-	30	-	-	-	-	30	-	-	-	30	-	-	120
7.9	Number of activations	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30 + 30	540
7.10	Test for back pressure - unactivated	60	60	60	60	60	60	60	60	60	60	30	30	30	30	60	60	60	900
7.11	Test for priming volume	30	-	-	-	-	30	-	-	-	-	30	-	-	-	30	-	-	120
7.12	Test for residual volume	30	-	-	-	-	30	-	-	-	-	30	-	-	-	30	-	-	120
7.13	Test for Displacement	30	-	-	-	-	30	-	-	-	-	30	-	-	-	30	-	-	120
7.14	Test for exposure to IPA.	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510
7.15	Duration of activation unactivated-state	60	60	60	60	60	60	60	60	60	60	30	30	30	30	60	60	60	900
7.16	duration of activation+ Infusate compatibility activated-state	60	60	60	60	60	60	60	60	60	60	30	30	30	30	60	60	60	900
7.17	Gauge insertion force	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510
7.18	Tensile force test as per ISO 8536-4	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510
7.19	Product NIP US welding strength test	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	510
7.20	Lipid	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	900

Product Name		Group#																	Total
	Resistance of Female Connector																		
Total:		694	540	540	540	540	694	540	540	540	540	540	390	390	390	690	540	540	9188

6.8. Traceability Table - Requirements vs. Tests:

MRD Section Number	PRD Section Number*	PRD Requirement	Risk Number in Design FMEA	Design V&V Section#	Passed / Failed	Remarks *See notes below*
N.R.	4.4.1	Materials	Rsk#1	-	TBD	Biocompatibility test see clause 4.15
N.R.	4.4.2	Raw Materials Regulatory Evaluation	-	-	Pass	See clause 3.11
N.R.	4.4.3	Sterilization compatibility	Rsk#8	-	Pass	See clause 4.5
N.R.	4.4.4	Shelf life	Rsk#7	-	Pass	See clause 4.7
N.R.	4.4.5	Non interconnectability	Rsk#5	-	Pass	See clause 4.1
N.R.	4.4.6	Mechanical resistance- positive pressure fluid leakage	Rsk#3	7.4	Pass	-
N.R.	4.4.7	Mechanical resistance- Sub atmospheric pressure air leakage	Rsk#3	7.5	Pass	-
N.R.	4.4.8	Mechanical resistance- Stress cracking	Rsk#5	7.20	Pass	-
N.R.	4.4.9	Mechanical resistance – Resistance to separation from axial load	Rsk#5	-	Pass	See clause 4.1
N.R.	4.4.10	Mechanical resistance – Resistance to separation from unscrewing	Rsk#10	-	Pass	See clause 4.1
N.R.	4.4.11	Mechanical resistance- Resistance to overriding	Rsk#5	-	Pass	See clause 4.1
N.R.	4.4.12	Air Leakage as per ISO 8536-4	Rsk#11	7.6	Pass	-
N.R.	4.4.13	Sub atmospheric-pressure air leakage	Rsk#5	7.5	Pass	-
N.R.	4.4.14	Low Pressure Air Leakage	Rsk#5	7.6	Pass	-
N.R.	4.4.15	Liquid Leakage	Rsk#6	7.4	Pass	-
N.R.	4.4.16	Duration of activation	Rsk#9,11	7.15, 7.16	Pass	-
N.R.	4.4.17	Long term leakage	Rsk#9,11	7.15, 7.16	Pass	-
N.R.	4.4.18	Burst test	Rsk#6	7.7	Pass	-
N.R.	4.4.19	Flow rate	Rsk#5	7.8	Pass	-
N.R.	4.4.20	Number of activations	Rsk#5,6	7.9	Pass	-
N.R.	4.4.21	Welding strength	Rsk#5	7.18, 7.19	Pass	-
N.R.	4.4.22	Priming volume	Rsk#5	7.11	Pass	-
N.R.	4.4.23	Residual volume	Rsk#5	7.12	Pass	-
N.R.	4.4.24	Displacement	Rsk#5	7.13	Pass	-
N.R.	4.4.25	Durability to drugs and disinfection agents	Rsk#2	7.14, 7.20	Pass	-

MRD Section Number	PRD Section Number*	PRD Requirement	Risk Number in Design FMEA	Design V&V Section#	Passed / Failed	Remarks *See notes below*
N.R.	4.4.26	Microbial ingress (Swabability and microbial barrier)	Rsk#2	7.20	TBD	Will be updated after final results, results will be in different report by Milouda laboratories.
	4.4.27	Product functionality- Gauge insertion force	Rsk#4	7.17	Pass	-
N.R.	4.4.28	Tensile test as per ISO 8536-4	-	7.18, 7.19	Pass	-
	4.4.29	Test for back pressure -un-activated		7.10	Pass	-
N.R.	4.4.30	Packaging configuration	-	-	N.R	See clause 4.8
N.R.	4.4.31	Labeling configuration	-	-	N.R	
N.R.	4.4.32	Storage	-	-	N.R	-
N.R.	4.4.33	Elcam Spec. 0090-G Rev D. NIP	Rsk#1	7.3, 7.15, 7.17, 7.20	Pass	-
N.R.	4.4.34	Geometry	Rsk#12	7.1, 7.2	Pass	-

7. Design Verification Test Details

Laboratory test results for groups F:

PRJ-0695-Group F-tests results.xls

7.1. 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:	30 products from groups C4-5-60-ET & F5-5-60-EG.
Equipment:	MANTISx4- Visual Inspection Microscope
Treatments:	According to table on section #6.4.
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 #6.7
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:	See above tests results sheet 7.1 for groups C4-5-60-ET & F5-5-60-EG. No findings of visual defects were detected. All slits were opened after one activation with Luer slip syringe.
Discussion and Conclusion:	In old tests conducted on the previous raw material, we observed that the slit may be closed after gamma sterilization exceeding 25 kGy. In contrast, in the tests performed here on valves with the new raw material PN590422, we did not observe any instances of slit closure, even with sterilization above 40 kGy. =>Pass

7.2. Test Name: Septum and NIP Stand-Alone dimensions measurement.

Responsibility	Elcam Measurement laboratory
Purpose:	Verifying product's compliance to the drawings PN590422 & PN22808L.
Test Applicability:	Verifying that the products comply to the drawings and all the dimensions are within the tolerances
Risk Addressed by test:	Not meeting drawings dimensions and tolerances.
Tested Device:	4 parts of Septum PN 590422. 4 Samples of NIP Stand-Alone product PN 220808L.
Equipment:	VERTEX, Measuring pins, TRIMOS, CMM, BROSH
Treatments:	N.R. measurement should be performed on Septum without additional treatment. According to table on section #6.4.
Test Method (protocol):	According to Elcam's procedure 2-12-16 (Rev. 10).
Sample size:	4 parts of Septum PN 590422. 4 Samples of NIP Stand-Alone product PN 220808L.
Acceptance criteria:	Dimensions are within tolerances as defined in drawings 590422 and 220808L. In case of a deviation from the tolerance, it should be approved by the design engineer and quality engineer.
Results:	Dimensions measurement reports: See Doc-332096 &Doc-332095. All measured dimensions were within the tolerances in drawings PN590422 & PN22808L. For Septum PN590422 -see test also report and molding validation received by the supplier Doc-311086.
Discussion and Conclusion:	=>Pass

7.3. Test Name: Particulate contamination test acc. USP 788 Particles mater in Injection.

Responsibility	Elcam's Laboratory
Purpose:	The fluid pathway surfaces shall be smooth and clean of particles
Test Applicability:	Particulate contamination test of the NIP Stand-Alone product according to USP 788
Risk Addressed by test:	No meeting particulate contamination requirements, according to spec. ISO CN27 section 9.
Tested Device:	According to table on section #6.7

Equipment:	Beckman HIAC 9703+ instrument; in order to check particles in the medical device fluid path.
Treatments:	According to table on section #6.4.
Test Method (protocol):	According to SOP no. 4-02-64, Rev. 1, clause 4.6.2. - Connect every 10 products together. - Take 50 ml free-particle water with a syringe and wash the fluid path with water and collect the water to a container/small bottle. - Open the fluid paths and collect the water residues into the small bottle. - Repeat steps above until you wash all the rest of products. overall quantity of water: 75 ml - Inspect the particles size and quantity by HIAC 7903+ + by using program USP 43 <788> Test 1.B (<=100 ml water). - According to the inspection program the program disregards the first run and averages the three next runs.
Sample size:	According to table on section #6.7
Acceptance criteria:	Test 1.B (Solutions for parenteral infusion or solutions for injection supplied in containers with a nominal content of less than 100 mL) – The preparation complies with the test if the average number of particles present in the units tested does not exceed 6000 per container equal to or greater than 10 µm and does not exceed 600 per container equal to or greater than 25 µm.
Results:	Results can be seen in laboratory results for products, sheet 7.3 for groups F & C. Tests of particulate contamination in all groups revealed no minor particulate, and no particles over 1.00 mm (1,000 microns).
Discussion and Conclusion:	=> Pass

7.4. 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 #6.7
Equipment:	- Barometer - Stopwatch - Air pressure source line - Water with colorant
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	According to Elcam procedure 4-02-67, there shall be no leakage of water during 35 sec.
Results:	Results can be seen in laboratory results, sheet 7.4 (1) and (2) for groups F & C.

	Test 7.4 (1) show visual test results after performing multiple activation. Test 7.4 (2) show test results after applying pressure of 330 Kpa pressure.
Discussion and Conclusion:	All the tested products pass the visual and leakage tests. => Pass

7.5. 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 #6.7
Equipment:	Vacuum pump with a vacuum gauge. Rigid tube.
Treatments:	According to table on section #6.4.
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 #6.7
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:	Results can be seen in laboratory results, sheet 7.5 activated and unactivated, for groups F & C.
Discussion and Conclusion:	Test 7.5 activated- No leakage was found under vacuum pressure. Test 7.5 unactivated- No leakage was found under vacuum pressure. No entrance or movement of air bubble was found in both tests. => Pass

7.6. 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 #6.7
Equipment:	☐ Barometer ☐ Air pressure source line ☐ IV set ☐ Stopwatch
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	Products should not leak at a pressure of 0.5 bar for 15 sec., under water temperature at 40°C.
Results:	Results can be seen in laboratory results, sheet 7.6, for groups F & C.
Discussion and Conclusion:	No leakage of air was found in all tested products. => Pass

7.7. 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 #6.7
Equipment:	HBLT Model 2000 made by Crescent, distilled water.
Treatments:	According to table on section #6.4.
Test Method (protocol):	According to Elcam's SOP 4-02-45 Rev. 5, program: HR Valve Burst. 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 #6.7
Acceptance criteria:	According to Elcam procedure 4-02-45 Rev. 5, there shall be no leakage of water below pressure of 30 PSI.

Results:

Results can be seen in laboratory results, sheet 7.7, for groups F & C.

Groups	C4	F5
	Max. [PSI]	Max. [PSI]
AVERAGE	43.0	45.1
STDEV	2.5	3.0
MAXIMUM	45.9	50.4
MINIMUM	40.1	40.2
x+3sd	50.4	54.2
x-3sd	35.6	36.0

Discussion and Conclusion:

Based on the burst pressure results, Group F demonstrated an average of approximately 45 PSI, compared to an average of 43 PSI in Group C. From these results, we can conclude that both valves respond almost identically to burst pressure. The minimum allowable burst pressure is 30 PSI, therefore the new valve exceeds the requirement and is approved.
=> Pass

7.8. Test Name: Verification of flow rate.

Responsibility	Elcam's Laboratory.
Purpose:	Verifying the product flow is according to ANSI/AAMI CN27 Sec. 5.1.
Test Applicability:	Ensure that the valve meets the flow requirement for an infusion set. Rate flow of over 1000 cc for 10 minutes at gravity of 1 meter of water.
Risk Addressed by test:	Risk of non-compliance with the product flow requirement, according to ANSI/AAMI CN27 Sec. 5.1.
Tested Device:	According to table on section #6.7
Equipment:	A water tank at a height of 1 meter. Nip-connected tube to IV infusion set. Sealine 0.9%. Stopwatch Clean and dry measuring cup
Treatments:	According to table on section #6.4.
Test Method (protocol):	According to Elcam procedure 4-02-67 sec.6.4. Open the water flow for at least half a minute. Weigh the amount of liquid received and calculate the system flow in ml/min.
Sample size:	According to table on section #6.7
Acceptance criteria:	Flow rate is over 120 ml per minute.
Results:	Results can be seen in laboratory results, sheet 7.8, for groups F & C.

Groups	C4	F5
	Max. [ml/min.]	Max. [ml/min.]
AVERAGE	363.0	367.9
STDEV	19.9	9.5
MAXIMUM	388.3	384.0

	MINIMUM 278.7 347.8
Discussion and Conclusion:	In both groups, we obtained flow rate results exceeding 360 ml/min, which is three times higher than the requirement specified in the standard. => Pass.

7.9. 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 #6.7
Equipment:	Infusion set, Air compressor, barometer, colored water, LLOYD measurement machine.
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	there shall be no leakage of water at 2 bar over 15 minute at 40°C.
Results:	Results can be seen in laboratory results, sheet 7.9 A & B, for groups F. Test 7.9(1) left page- show visual test after performing multiple activations **Luer slip**. Test 7.9(1) right page-show visual test after performing multiple activations **Luer lock** Test 7.9 (2) left page- show test results after applying pressure of 2 Bar over 15 minutes for **Luer slip**. Test 7.9 (2) right page-show test results after applying pressure of 2 Bar over 15 minutes for **Luer lock.**
Discussion and Conclusion:	During the visual inspection, small tear marks were observed on the valve, both along the slit direction and at an angle to it. These minor tears are acceptable and were caused by the multiple **Luer lock** activations. All products withstood the pressure of 2 bar for 15 minutes at 40°C after the multiple **Luer lock** and **Luer slip** activations, in both groups. => Pass.

7.10. 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 #6.7
Equipment:	Colored water, air pressure source.
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	The LAV shall show no signs of leakage over the hold period consistent with the high and low pressures.
Results:	Results can be seen in laboratory results, sheet 7.10 for groups F & C.
Discussion and Conclusion:	No leakages were found in back pressure at 0.5 and 2 bar during 35 sec. => Pass

7.11. Test Name: Test for priming volume.

Responsibility	Elcam's Laboratory
Purpose:	To determine the priming volume for Stand Alone product according to ISO CN27 spec 4-02-67 sec 6.12.
Test Applicability:	Volume shall be determined after priming the valve according to test method.
Risk Addressed by test:	Not meeting spec ISO CN27 sec.5.13.
Tested Device:	According to table on section #6.7
Equipment:	Syringe, colored water
Treatments:	According to table on section #6.4.
Test Method (protocol):	1. Use a 1 ml syringe, fill it with colored water, attach the syringe to the valve end of the LAV. 2. Fill the valve with a syringe with colored water until the product is full of liquid. 3. Record the change in the volume of the syringe.
Sample size:	According to table on section #6.7
Acceptance criteria:	Priming volume should be between 0.1 to 0.2 ml.
Results:	Results can be seen in laboratory results, sheet 7.11 for groups F & C.
Discussion and Conclusion:	According to results the Priming volume are between 0.1 to 0.2 ml. => Pass.

Groups	C1	F2
	Max. [ml.]	Max. [ml.]
AVERAGE	0.13	0.14
STDEV	0.01	0.01
MAXIMUM	0.16	0.16
MINIMUM	0.12	0.12

7.12. Test Name: Test for residual volume.

Responsibility	Elcam's Laboratory

Purpose:	To determine the residual volume for Stand Alone product according to ISO CN27 spec 4-02-67 sec 6.13.
Test Applicability:	Measure residual volume of the fluid pathway of the LAV in the unactivated or closed state.
Risk Addressed by test:	Not meeting spec ISO CN27 sec. 5.14.
Tested Device:	According to table on section #6.7
Equipment:	Syringe, colored water, scale
Treatments:	According to table on section #6.4.
Test Method (protocol):	1. Weigh the empty Stand Alone. 2. Use a 1 ml syringe, fill it with colored water, attach the syringe to the valve end of the LAV. 3. Use a male connector to fill the product. 4. Disconnect the connector and make sure the Stand-Alone Product is full, disconnect it from the syringe. 5. Weigh the full product. 6. Subtract the dry weight from the filled weight and convert to volume. 7. Record the volume in milliliter (ml).
Sample size:	According to table on section #6.7
Acceptance criteria:	Residual volume should be between 0.1 to 0.2 ml.
Results:	Results can be seen in laboratory results, sheet 7.12 for groups F & C.

Groups	C1	F2
	Max. [ml.]	Max. [ml.]
AVERAGE	0.13	0.15
STDEV	0.01	0.01
MAXIMUM	0.16	0.16
MINIMUM	0.12	0.14

Discussion and Conclusion:	According to results the Residual volume are between 0.1 to 0.2 ml. => Pass.

7.13. Test Name: Test for Displacement.

Responsibility	Elcam's Laboratory
Purpose:	To determine the displacement of fluid in and out of the LAV during disconnection. According to ISO CN27 sec 5.18.
Test Applicability:	Displacement of fluid shall be measured according to ISO CN27 sec 5.18.
Risk Addressed by test:	Not meeting spec ISO CN27 sec.5.18.
Tested Device:	According to table on section #6.7
Equipment:	Clear tube with ID3mm, Luer lock Syringe, colored water, clean container.
Treatments:	According to table on section #6.4.
Test Method (protocol):	Test method according to Elcam SOP 4-02-67 sec.6.15. 1. For the test, prepare a transparent tube with an internal diameter of 3 mm, connected at the end of the female Luer connector and cut perpendicular to the length of the tube at the other end. 2. Fill a small container with colored liquid. 3. Connect a **Luer lock** syringe to the LAV valve of the product. 4. Draw the colored water from the container into the product with the syringe.

	Ensure that the liquid fills the cavity of the tube and the product, and that there are no air bubbles 5. Invert the system (syringe, product, and tube) so that the tube opening faces upward. 6. Ensure that the liquid reaches the edge of the tube (if there is excess liquid, remove the drop; if there is a deficiency, add liquid from the syringe). 7. Disconnect the syringe from the LAV. 8. Measure with a caliper the height of the space created from the upper edge of the tube to the liquid line. 9. Calculate the volume by the equation $V=\pi r^2 h$, and record the change of the liquid volume in the tube.
Sample size:	According to table on section #6.7
Acceptance criteria:	Priming volume should be: 1. The displacement volume of the space created as a result of disconnection of the Luer lock syringe < 0.05 mL 2. The displacement volume of the space created as a result of disconnection of the Luer slip syringe < 0.10 mL
Results:	Results can be seen in laboratory results, sheet 7.13 for groups F & C. The test was performed with **Luer lock** syringe (most severe test) according to Elcam SOP 4-02-67 sec.6.15.

Groups	C1	F2
	Volume [ml.]	Volume [ml.]
AVERAGE	0.02	0.02
STDEV	0.01	0.00
MAXIMUM	0.03	0.03
MINIMUM	0.00	0.01

Discussion and Conclusion:	According to results the displacement volume are lower than 0.05 ml. => Pass.

7.14. 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 #6.7
Equipment:	IPA, Air compressor, barometer, colored water.
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	Not one drop may be released during 35 sec. in 0.5 and 2 bar.
Results:	Results can be seen in laboratory results, sheet 7.14 for groups F & C.
Discussion and	The products didn't leak for 35 sec under pressure of 0.5 and 2 bar, after exposing to IPA.

Conclusion:	Both groups C & F have passed successfully. => Pass.

7.15. 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 #6.7
Equipment:	Barometer Stopwatch Air pressure source line Water with red colorant
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	According to Elcam procedure 4-02-20, there shall be no leakage of water during all test period.
Results:	Results can be seen in laboratory results, sheet 7.15 for groups F & C.
Discussion and Conclusion:	Tested products during 11 days, didn't leak at pressure of 0.5 and 2 bar. => Pass.

7.16. 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 #6.7
Equipment:	Infusion set, Air pressure source line, barometer, Stopwatch, colored water.
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	Not one drop may be released during all test period of 11 days at pressure of 0.2 and 2 bar.
Results:	Results can be seen in laboratory results, sheet 7.16 for groups F & C. Tested products after 11 days, didn't leak for 35 sec in 0.5 and 2 bar.
Discussion and Conclusion:	Both groups C & F have passed successfully. => Pass.

7.17. 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 #6.7
Equipment:	LLOYD machine, gauge LA001114265
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	Activation force AVG X ≤ 30 N Load At Max. insertion.
Results:	Results can be seen in laboratory results, sheet 7.17 for groups F & C. Group F5: average insertion force of 22.5 N. Group C4: average insertion force of 16.7 N.
Discussion and Conclusion:	Based on the results from all groups, we observe that as the product undergoes stronger Gamma irradiation, the valve becomes harder. For example, in the results of Group A (which is without irradiation), the mean result is approximately 16 N, like group C (which is also without irradiation). Group F, with the highest irradiation level of more than 40 kGy, reaches insertion force of 22.5 N. Therefore, we are still much below the maximum allowed insertion force of 30 N. Both groups C & F have passed successfully. => Pass.

Groups	A4	B4	C4	F5
AVG (mean)	16.2	18.2	16.7	22.5
STD	0.4	0.7	0.7	1.1
Max.	17.6	19.75	18.0	23.5

7.18. 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 #6.7
Equipment:	Lloyd Testing Machine
Treatments:	According to table on section #6.4.
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 #6.7
Acceptance criteria:	Components withstand a static tensile force of 15 N for 15 sec.
Results:	Results can be seen in laboratory results, sheet 7.18 for groups F & C. All products pass the Tensile force test as per ISO 8536-4 Sec. 7.3
Discussion and Conclusion:	Groups F5 & C4 F have passed successfully. => Pass.

7.19. 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 #6.7
Equipment:	Torque meter S.N. 221415 Adaptor device LA031280207
Treatments:	According to table on section #6.4.
Test Method (protocol):	According to Elcam SOP 4-02-53 (Rev 8) clause 6.2.
Sample size:	According to table on section #6.7
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:	Results can be seen in laboratory results, sheet 7.19 for groups F. All products from group F5 pass the Tensile force test applied at the US welding area, with a Torque of 140 In•Oz in the two tested direction.
Discussion and Conclusion:	Groups F5 have passed successfully. => Pass.

7.20. 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 #6.7
Equipment:	Infusion set, Air pressure source line, barometer, Stopwatch, colored water.
Treatments:	According to table on section #6.4.
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 #6.7
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:	Results can be seen in laboratory results, sheet 7.20 for groups F & C. There is no leakage as a result of exposure to lipid as detailed in the above procedure.
Discussion and Conclusion:	Both groups F5 & C4 have passed successfully, during product usage life of 11 days. => Pass.

7.21. Microbial ingress (Swabability and microbial barrier) according to ANSI/AAMI CN27 Sec. 5.17. This test was conducted by external laboratory Mérieux NutriSciences and supervisory by Elcam QA department. See Doc-330808.

8. Discussion and Conclusions

8.1. Discussions and conclusions are included within each test section.

8.2. Based on visual inspections, we have observed that the new raw material demonstrates greater resistance to tears and deformations compared to Group C, which utilizes the older raw material. Furthermore, in previous project testing, product failures occurred after sterilization exceeding 25 kGy. Conversely, with the new raw material, the product remains compliant even after Gamma irradiation at 47.3 kGy (see section 6.2.4). Therefore, we conclude that the new raw material is superior in terms of resistance to tears, deformation, and maintaining sealing integrity, even after undergoing Gamma irradiation of min 42.8 kGy.

8.3. This report details all functional tests conducted according to the standard AAMI ISO CN27-2021 (Part 2: Performance requirements).

8.4. All tests for all groups have been completed successfully.

8.5. Based on these results, it can be concluded that Elcam’s products that contains Luer activated valves PN590422 with the new silicon SILPURAN® 6000/50 A+B are compliant with AAMI ISO CN27-2021.

9. Manufacturing Comments

9.1. Given that only the valve's raw material has been replaced, without altering the valve's design or properties, no changes to assembly or production processes are necessary.

10. Recommendations

10.1. Based on all above the tests results, all Elcam’s products containing the new Luer activated valves PN590422 with the new silicon SILPURAN® 6000/50 A+B, can be approved for a five years shelf life, after undergoing up to 42.8 kGy Gamma irradiation and two cycles of EtO sterilization. Furthermore, the new silicon valve PN590422 is approved for multiple activations (engagements and disengagements to female port with male Luer) of **140 male Luer slip** or **140 male Luer lock**.

11. Revision Tracking

Revision Number	Revision date	Change description	Changed by
A	6-Apr-2025	First version	Israel. L.

12. Approval

Position	Name	Date	Signature
Product Engineer	-	-	-
CTO/R&D Manager	-	-	-
QE Manager / Chief Quality & Regulatory Officer	-	-	-

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