

		Sterilization report for Specialmekaniska products	F 43-INM-MDV Version 1
Issue date	03.03.2025		

Sterilization report Nr. 1/05.03.2025.

Customer/order information

Customer	Specialmekaniska (InkMachine)
Order No	2025-02-2025
Incoming date	28.02.2025
Customers reference	2025-02-2025
Product	Ink cartridges
Sterilization cycle name	BSA MDV
Sterilization date	03.03.2025
Sterilization batch/cycle	19030205
Load (volume/weight)	1EP, 350kg, 1.44m3
Sterilization chamber	SR2SH18
Precondition chamber	PCII
Aeration chamber	DGI

Sterilization cycle review

No.	Parameter	Unit	Acceptance criteria			Pass/Fail
			MIN.	Actual	MAX.	
Preconditioning						
1.	Temperature	°C	40	45	50	Pass
2.	Humidity	RH (%)	40	55	80	Pass
3.	Time	h	15	16	18	Pass
Transfer						
4.	Transfer time	min	NA	5	15	Pass
EO Chamber						
5.	Vacuum pressure	mbar	40	60	60	Pass
6.	Vacuum time	min	NA	8	45	Pass
7.	Low pressure stabilization time	min	5	5	6	Pass
8.	Low pressure leak test time	min	5	5	6	Pass
9.	Maximum pressure leak	mbar	NA	1	15	Pass
10.	Nitrogen injection pressure	mbar	640	660	660	Pass
11.	Nitrogen injection quantity	qty	1	1	1	Pass
12.	Vacuum pressure	mbar	40	60	60	Pass
13.	Steam pressure rise	mbar	35	45	45	Pass
14.	Humidity (end of injection)	RH (%)	40	100	NA	Pass
15.	Humidity stabilization time	min	35	45	45	Pass
16.	Humidity (end of stabilization)	RH (%)	40	68	NA	Pass
17.	1 st EO injection	Δ mbar	150	180	180	Pass
18.	1 st EO injection time	min	NA	5	NA	Pass
19.	EO injection temperature	°C	15	30	80	Pass
20.	1 st Nitrogen injection	Δ mbar	80	111	120	Pass

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21.	2 nd EO injection	Δ mbar	280	300	300	Pass
22.	2 nd EO injection time	min	NA	9	NA	Pass
23.	EO injection temperature	°C	15	30	80	Pass
24.	Last Nitrogen injection	Δ mbar	30	59	70	Pass
25.	EO weight (total weight injected)	kg	2,5	3.81	4,5	Pass
26.	Exposure time	min	359	360	365	Pass
27.	Exposure temperature	°C	40	48	50	Pass
28.	EO concentration (calculation)	mg/l	700	792	800	Pass
29.	Satisfactory operation of gas recirculation system (Y/N)	Y/N	NA	Y	NA	Pass
Post Exposure Rinsing						
30.	Vacuum pressure	mbar	50	63	80	Pass
31.	Nitrogen injection pressure	mbar	450	506	600	Pass
32.	Nitrogen rinsing	qty	2	2	2	Pass
33.	Vacuum pressure	mbar	50	63	80	Pass
34.	Air injection pressure	mbar	750	805	850	Pass
35.	Air rinsing	qty	5	5	5	Pass
Post-Conditioning						
36.	Temperature	°C	35	47	50	Pass
37.	Time	h	24	24	36	Pass

Process control

Biological indicator (Bac.Atrophaeus)	MesaLab 5.62
Number of BI	6
BI LOT	B230412 33PE6A
BI expiry date	05.07.2025
Test time	48h
Result (PASS/FAIL)	Pass
End date of control	05.03.2025
Conclusion	The incubation of the EPCDs used for monitoring of this cycle showed no growth.

Conclusion

The EO sterilized batch, performed according to ISO 11135:2014 standard, was in compliance with Osmunds approved cycle specifications for Specialmekaniska (InkMachine) products.

Date: 05.03.2025

R. Baranovskis
Managing director of sterilization center

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Quality management system certified according LVS EN ISO 9001:2015, LVS EN ISO 11135:2014 and LVS EN ISO 13485:2016. Issued by "Bureau Veritas Certification".