

		<b>Sterilization report for Specialmekaniska products</b>	<b>F 43-INM-MDV</b> Version 1
Issue date	03.03.2025		

## Sterilization report Nr. 2/30.07.2025.

### Customer/order information

Customer	Specialmekaniska (InkMachine)
Order No	N/A
Incoming date	10.07.2025
Customers reference	N/A
Product	Ink cartridges
Sterilization cycle name	BSA MDV
Sterilization date	11.07.2025
Sterilization batch/cycle	3071105
Load (volume/weight)	1EP, 376kg, 2,05m3
Sterilization chamber	SR2SH18
Precondition chamber	PCI
Aeration chamber	DGI

### Sterilization cycle review

No.	Parameter	Unit	Acceptance criteria			Pass/Fail
			MIN.	Actual	MAX.	
<b>Preconditioning</b>						
1.	Temperature	°C	40	45	50	Pass
2.	Humidity	RH (%)	40	58	80	Pass
3.	Time	h	15	16	18	Pass
<b>Transfer</b>						
4.	Transfer time	min	NA	5	15	Pass
<b>EO Chamber</b>						
5.	Vacuum pressure	mbar	40	60	60	Pass
6.	Vacuum time	min	NA	10	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	74	NA	Pass
17.	1 <sup>st</sup> EO injection	Δ mbar	150	180	180	Pass
18.	1 <sup>st</sup> EO injection time	min	NA	4	NA	Pass
19.	EO injection temperature	°C	15	38	80	Pass
20.	1 <sup>st</sup> Nitrogen injection	Δ mbar	80	105	120	Pass

		<b>Sterilization report for Specialmekaniska products</b>	<b>F 43-INM-MDV</b> Version 1
Issue date	<b>03.03.2025</b>		

21.	2 <sup>nd</sup> EO injection	Δ mbar	280	300	300	Pass
22.	2 <sup>nd</sup> EO injection time	min	NA	8	NA	Pass
23.	EO injection temperature	°C	15	38	80	Pass
24.	Last Nitrogen injection	Δ mbar	30	60	70	Pass
25.	EO weight (total weight injected)	kg	2,5	3.93	4,5	Pass
26.	Exposure time	min	359	360	365	Pass
27.	Exposure temperature	°C	40	47	50	Pass
28.	EO concentration (calculation)	mg/l	700	794	800	Pass
29.	Satisfactory operation of gas recirculation system (Y/N)	Y/N	NA	Y	NA	Pass
<b>Post Exposure Rinsing</b>						
30.	Vacuum pressure	mbar	50	60	80	Pass
31.	Nitrogen injection pressure	mbar	450	505	600	Pass
32.	Nitrogen rinsing	qty	2	2	2	Pass
33.	Vacuum pressure	mbar	50	63	80	Pass
34.	Air injection pressure	mbar	750	804	850	Pass
35.	Air rinsing	qty	5	5	5	Pass
<b>Post-Conditioning</b>						
36.	Temperature	°C	35	45	50	Pass
37.	Time	h	24	24	36	Pass

### Process control

Biological indicator (Bac.Atrophaeus)	MesaLab 5.13
Number of BI	6
BI LOT	B250081 G-251
BI expiry date	02.12.2025
Test time	48h
Result (PASS/FAIL)	Pass
End date of control	13.07.2025
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: 30.07.2025

R. Baranovskis  
Managing director of sterilization center

		<b>Sterilization report for Specialmekaniska products</b>	<b>F 43-INM-MDV</b> Version 1
Issue date	<b>03.03.2025</b>		



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".