

		<b>Sterilization report for Specialmekaniska products</b>	<b>F 43 - INM</b> Version 3
Issue date	<b>02.12.2021</b>		

## Sterilization report Nr. 3/05.09.2023.

### Customer/order information

Customer	Specialmekaniska (InkMachine)
Order No.	Aug-23
Incoming date	01.09.2023.
Customers reference	CMR 25.08.2023.
Product	Ink cartridges
Sterilization cycle name	Cycle 01
Sterilization date	02.09.2023.
Sterilization batch/cycle	00014090210
Load (volume/weight)	1,8 m <sup>3</sup> 320 kg 16 cartoons

### Sterilization cycle review

STEP #	STEP	UNIT	MIN.	Actual	MAX.	Pass/Fail
1.	Acclimatization (Incoming goods area)	°C	15	20	NA	Pass
2.	Preconditioning	°C	45	46	55	Pass
		%Rh	40	50	75	Pass
		h	12	12	14	Pass
3.	Transfer time	Mins	NA	4	18	Pass
4.	Initial Vacuum Pull	Mba	45	53	55	Pass
5.	Low Pressure Stabilization Time	Mins	4	5	6	Pass
	Low Pressure Leak Test Time	Mins	2	2	2	Pass
	Maximum Pressure Leak	Δ Mbar	-	0	15	Pass
6.	Nitrogen Injection	Δ Mbar	550	612	650	Pass
7.	Vacuum Pull	Mbar	45	53	55	Pass
8.	Steam Injection (Record Humidity Only)	Δ Mbar	27	30	33	Pass
		%RH	-	90	-	Pass
9.	Humidification Dwelll	mins	27	30	30	Pass
		%RH	-	90	-	Pass
		°C	40	50	50	Pass
		Mbar	62	72	88	Pass
10.	1 <sup>st</sup> EO Injection	Δ Mbar	300	300	300	Pass
		°C	15	40	NA	Pass
		mins	x	8	Y	Pass
		kg	2,0	2,5	-	Pass
11.	1 <sup>st</sup> Nitrogen Injection	Δ Mbar	200	200	200	Pass
12.	2 <sup>nd</sup> EO Injection	Δ Mbar	100	100	100	Pass
		°C	15	40	NA	Pass
		mins	X	3	y	Pass
		kg	0,7	0,8	-	Pass
13.	2 <sup>nd</sup> Nitrogen Injection	Δ Mbar	100	100	100	Pass
14.	EO dwell	Mins	180	180	190	Pass
		°C	52	55	58	Pass
		%RH	-	82	-	Pass
		mg/L	700	700	800	Pass
15.	Satisfactory Operation of Recirculation System	Y/N	Y	Y	Y	Pass
16.	Post EO Evacuation	Mbar	55	61	65	Pass

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		mins	-	10	-	Pass
17.	Nitrogen Rinsing	Qty	2	2	2	Pass
	Nitrogen Rinsing Injection	Mbar	450	507	550	Pass
	Nitrogen Rinsing Vacuum	Mbar	55	60	65	Pass
	Air Rinsing	Qty	5	5	5	Pass
18.	Air Rinsing Injection	Mbar	750	800	850	Pass
	Air Rinsing Vacuum	Mbar	55	60	65	Pass
	Nitrogen/Air Rinsing	mins	NA	293	NA	Pass
20.	Heated aeration	°C	45	49	55	Pass
		h	24	24	36	Pass

### Process control

Biological indicator (Bac.Atrophaeus)	Etigam
Number of BI	4
BI LOT	5271
BI Expiry date	30.06.2023.
Test time	48h
Result (PASS/FAIL)	Pass
End date of control	04.09.2023.
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 complied with Osmunds approved cycle specifications for Specialmekaniska (InkMachine) product.

Date: 05.09.2023.

R. Baranovskis  
Managing director of sterilization center



Quality management system certified according LVS EN ISO 9001:2015, LVS EN ISO 11135:2014 and LVS EN ISO 13485:2016.

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