

		Sterilization report for Specialmekaniska products	F 43 - INM Version 3
Issue date	02.12.2021		

Sterilization report Nr. 4/21.11.2023.

Customer/order information

Customer	Specialmekaniska (InkMachine)
Order No.	Nov-08
Incoming date	14.11.2023.
Customers reference	CMR 14.11.2023.
Product	Ink cartridges
Sterilization cycle name	Cycle 01
Sterilization date	15.11.2023.
Sterilization batch/cycle	0007111501
Load (volume/weight)	3,55 m ³ 660 kg 32 cartoons

Sterilization cycle review

STEP #	STEP	UNIT	MIN.	Actual	MAX.	Pass/Fail
1.	Acclimatization (Incoming goods area)	°C	15	15	NA	Pass
2.	Preconditioning	°C	45	45	55	Pass
		%Rh	40	46	75	Pass
		h	12	13	14	Pass
3.	Transfer time	Mins	NA	6	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	-	88	-	Pass
9.	Humidification Dwelll	mins	27	30	30	Pass
		%RH	-	86	-	Pass
		°C	40	49	50	Pass
		Mbar	62	73	88	Pass
10.	1 st EO Injection	Δ Mbar	300	300	300	Pass
		°C	15	37	NA	Pass
		mins	x	12	Y	Pass
		kg	2,0	3.0	-	Pass
11.	1 st Nitrogen Injection	Δ Mbar	200	200	200	Pass
12.	2 nd EO Injection	Δ Mbar	100	100	100	Pass
		°C	15	37	NA	Pass
		mins	X	2	y	Pass
		kg	0,7	0,8	-	Pass
13.	2 nd Nitrogen Injection	Δ Mbar	100	100	100	Pass
14.	EO dwell	Mins	180	180	190	Pass
		°C	52	53	58	Pass
		%RH	-	67	-	Pass

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		mg/L	700	700	800	Pass
15.	Satisfactory Operation of Recirculation System	Y/N	Y	Y	Y	Pass
16.	Post EO Evacuation	Mbar	55	60	65	Pass
		mins	-	15	-	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
18.	Air Rinsing	Qty	5	5	5	Pass
	Air Rinsing Injection	Mbar	750	804	850	Pass
	Air Rinsing Vacuum	Mbar	55	60	65	Pass
19.	Nitrogen/Air Rinsing	mins	NA	62	NA	Pass
20.	Heated aeration	°C	45	49	55	Pass
		h	24	33	36	Pass

Process control

Biological indicator (Bac.Atrophaeus)	Etigam
Number of BI	4
BI LOT	5292
BI Expiry date	31.08.2024.
Test time	48h
Result (PASS/FAIL)	Pass
End date of control	17.11.2023.
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: 21.11.2023.

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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