

Sterilization report Nr. 1/28.04.2021.

Customer/order information

Customer	Specialmekaniska (InkMachine)
Order no.	1/20042021
Incoming date	22.04.2021.
Customers reference	Batch March-21;April-21
Product	Ink cartridges
Sterilization cycle name	Cycle 01
Sterilization date	26.04.2021.
Sterilization batch/cycle	7042610
Load (volume/weight)	1,786 m3 290 kg

Sterilization cycle review

PHASE	PARAMETER	UNIT		Minimum	Actual	Maximum	Status
							PASS/FAIL
Acclimatization (Incoming goods area)	Temperature	°C		15	15	NA	PASS
Preconditioning	Temperature	°C		35	44	45	PASS
	Relative humidity	%RH		45	50	75	PASS
	Time	h		12	13	14	PASS
Transfer time	Time	min		NA	7	18	PASS
	Evacuation pressure	mbarA		45	53	55	PASS
	Stabilization time	min		4	5	6	PASS
	Leak test	min		2	2	2	PASS
	Leak rate	mbar		NA	2	5	PASS
	Nitrogene pulsation	mbar		550	611	650	PASS
Humidification/ Steam conditioning	Humidification Δp	mbar		27	30	33	PASS
	Steam dwell time	min		27	30	33	PASS
	Steam dwell end pressure	mbarA		62	71	88	PASS
	Humidity of the chamber	Rh%		30	66	80	PASS
EO exposure	EO injection	mbarA		385	400	415	PASS
		min		NA	13	NA	PASS
		kg		2,7	3,64	NA	PAS*
	Gas injection temperature	°C		15	25	NA	PASS



	EO concentration at end of gas injection phase	mg/L		700	700	800	PASS
	EO dwell time	min		180	180	190	PASS
	Satisfactory of gas circulation	Y/N		NA	Y	NA	PASS
	EO dwell temperature	°C		52	54	58	PASS
	Evacuation time	min		NA	14	NA	PASS
Nitrogene/Air wash phase	Number of wash cycles Nitrogen			2	2	2	PASS
	Nitrogen Rinsing vacuum	mbar		55	60	65	PASS
	Nitrogene rinsing pressure	mbar		450	506	550	PASS
	Number of First Air rinsing steps			5	5	5	PASS
	Air wash 1st: rinsing vacuum	mbar		55	60	65	PASS
	Air wash 1st: rinsing pressure	mbar		750	803	850	PASS
	Time during flushing	min		NA	55	NA	PASS
Degassing	Temperature	°C		35	44	45	PASS
	Time	h		24	25	36	PASS

Biological indicator (Bac.Atrophaeus)	Etigam
Number of BI	4
Indicator LOT	5245
Test time	48h
Result (PASS/FAIL)	Pass
End date of control	28.04.2021.

Conclusion

The EO sterilized batch, perform according to ISO-11135:2104 standard complied with Osmunds approved cycle specifications for optical fiber product.

Date: 28.04.2021.

Cycle approved

R. Baranovskis
Managing director of sterilization centre