



## Sterilization report Nr. 1/17.03.2022.

### Customer/order information

Customer	Specialmekaniska (InkMachine)
Order no.	1/11032022
Incoming date	11.03.2022.
Customers reference	Batch March-22
Product	Ink cartridges
Sterilization cycle name	Cycle 01
Sterilization date	15.03.2022.
Sterilization batch/cycle	00030031510
Load (volume/weight)	1.49m3 11 boxes 300kg

### 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		40	47	50	PASS
	Relative humidity	%RH		45	55	75	PASS
	Time	h		12	12	14	PASS
Transfer time	Time	min		NA	5	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	1	5	PASS
	Nitrogene pulsation	mbar		550	612	650	PASS
Humidification/ Steam conditioning	Humidification $\Delta p$	mbar		27	30	33	PASS
	Steam dwell time	min		27	30	33	PASS
	Steam dwell end pressure	mbarA		62	76	88	PASS
	Humidity of the chamber	Rh%		30	51	80	PASS
EO exposure	EO injection	mbarA		385	400	415	PASS
		min		NA	12	NA	PASS
		kg		2,7	3,06	NA	PAS*
	Gas injection temperature	°C		15	22	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	7	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	65	65	PASS
	Air wash 1st: rinsing pressure	mbar		750	751	850	PASS
	Time during flushing	min		NA	56	NA	PASS
Degassing	Temperature	°C		35	52	55	PASS
	Time	h		24	24	36	PASS

Biological indicator (Bac.Atrophaeus)	Etigam
Number of BI	4
Indicator LOT	5260
Test time	48h
Result (PASS/FAIL)	Pass
End date of control	17.03.2022.

### Conclusion

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

Date: 17.03.2022.

Cycle approved

R. Baranovskis  
 Managing director of sterilization centre