



## Sterilization report Nr. 1/25.12.2020.

### Customer/order information

Customer	Specialmekaniska (InkMachine)
Order no.	1/12162020
Incoming date	21.12.2020.
Customers reference	Batch Dec-20
Product	Ink cartridges
Sterilization cycle name	Cycle 01
Sterilization date	28.11.2020.
Sterilization batch/cycle	24122310
Load (volume/weight)	1,916 m3 341,5 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	43	45	PASS
	Relative humidity	%RH		45	55	75	PASS
	Time	h		12	13	14	PASS
Transfer time	Time	min		NA	6	18	PASS
	Evacuation pressure	mbarA		45	50	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	614	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	71	88	PASS
	Humidity of the chamber	Rh%		30	61	80	PASS
EO exposure	EO injection	mbarA		385	400	415	PASS
		min		NA	10	NA	PASS
		kg		2,7	2,99	NA	PAS*
	Gas injection temperature	°C		15	21	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	53	58	PASS
	Evacuation time	min		NA	5	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	514	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	805	850	PASS
	Time during flushing	min		NA	55	NA	PASS
Degassing	Temperature	°C		35	45	45	PASS
	Time	h		24	25	36	PASS

Biological indicator (Bac.Atrophaeus)	Etigam
Number of BI	4
Indicator LOT	5240
Test time	48h
Result (PASS/FAIL)	Pass
End date of control	25.12.2020.

### Conclusion

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

Date: 28.12.2020.

Cycle approved

R. Baranovskis  
Managing director of sterilization centre