STERILIZATION REPORT

No: 1/21082018

OSMUNDS STERILIZĀCIJAS CENTRS
Siltuma ielā 4, Rīgā, LV – 1058, reģistrācijas Nr. 40003162732
Tālrunis/fakss +371 67 537 892, e-pasts: osmunds@osmunds.lv, www.osmunds.lv

1. ORDER INFORMATION

1.1.	**Order Reg. NO.:**	**Ink Machines**	**Customer Batch id:**	Aug-18		
1.2.	**Customer Name/ID:**	Ink Machines Sweden				
1.3.	**Product:**	**Neo-Cartridges**	**Number of Pallets:**	1	**Number of Boxes:**	16
1.4.	**Cycle selection:**	Lumenis:	Cycle01: X	Cycle03:	**Number of Runs:**	1
					Volume m3:	1.83

1.5. **Data of Arrival:** 13-08-18 **Time:** 13:00

1.6. **Temperature measurements of Incoming goods:**

1.6.1.	Min/Max Temperature of incomming goods °C:	Min:	25	Max:	24
1.6.2.	Set Acclimatiozation time for incomming goods, h:		NA	*Set value if less than 15°C, otherwise = 0*	

2. BATCH RECORDS

2.1. **Batch No:** 1 **Batch ID:** **Ink Machines 1**

2.1.1. **Batch identification/labeling:**

Pallets per Batch:	1	ID sticker Number:	13082018001
Boxes per Batch:	16	Cycle Number:	7081410

2.1.2. **Process Parameters:**

Parameter	Requirement	Actual	Pass/Fail
Preconditioning Hold	4-12h	11	Pass
Preconditioning Temperature	40-55°C	43	Pass
Preconditioning Relative Humidity	40-75%	49	Pass
Transfer to Sterilization Chamber	≤30min	10	Pass
Temperature of the load when entering sterilization chamber	min 35°C	41	Pass
Vacuum setpoint for Air removal	50 mBar	50	Pass
Maximum pressure increase during leak test	5 mBar	1	Pass
Nitrogen Addition	600+/-60mBar	619	Pass
Evacuation	40-60mBar	50	Pass

Set point for Humidification Pressure	50mBar	50	Pass
Steam injection time	3-10min	5	Pass
Humidity Stabilization time	30+/-3min	30	Pass
Humidity Dwell Pressure	100+/-30mBar	102	Pass
1st Nitrogen injection diff. pressure	0 mBar	0	Pass
1st ETO injection differential pressure	300+/-10mBar	300	Pass
2nd Nitrogen injection diff. pressure	200+/-30mBar	180	Pass
2nd ETO injection differential pressure	100+/-20mBar	100	Pass
Last Nitrogen injection diff. pressure	100+/-20mBar	120	Pass
Total ETO injection time	10-15min	10	Pass
Total Nitrogen injection time	20-40sec	30	Pass
Gas Dwell	Duration 240-0/+10min	180	Pass
	Temperature 50+/-5°C	54	Pass
	Gass Exposure pressure 720-800mBar	767	Pass
Time taken to evaquate the chamber	max 10min	7.5	Pass
Gas Wash (2 nitrogen, 6 Air pulsations)	(N2) = 65+/-15mBar	60	Pass
	(N2) = 500+/-50mBar	534	Pass
	(Air) = 60+/-10mBar	70	Pass
	(Air) = 800+/-80mBar	792	Pass
Post exposure flushing time	45-60min	60	Pass
Release	1000+/-200mBar	814	Pass
Aeration Temperature	40-50°C	43	Pass
Aeration Time	48-0/+12h	60	Pass
ETO gas consumption	2,7-3,3kg	3.3	Pass

2.1.3. **BI placement:**

2.1.3.1. **BI's Evaluation:**

Number of PASS results: 6 Number of FAIL results: 0

Number of BI's 6 LOT No: 5171 Exp.Data.: 06.2019.

3. PROCES SUMARY

3.1.	**Number of succsefull Batches:**	**1**
3.2.	**Number of succsesfully processed Pallets:**	**1**
3.3.	**Number of succsesfully processed Boxes:**	**16**
3.4.	**Number of deviation reports:**	**0**

Data: 21-08-18

Signature: _____

R.Baranovskis

Managing director of sterilization centre

All goods processed according to SIA "OSMUNDS STERILIZĀCIJAS CENTRS" quality control procedures and instructions.
Process certified under: LVS EN ISO 9001:2015, LVS EN ISO 11135:2014 and LVS EN ISO 13485:2016.