

STERILIZATION REPORT

No: 2/03122018



OSMUNDS STERILIZĀCIJAS CENTRS
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1. ORDER INFORMATION

1.1. Order Reg. NO.: **Ink Machines** Customer Batch id: November 18

1.2. Customer Name/ID: **Ink Machines Sweden**

1.3. Product: **NEO cartridges** Number of Pallets: 1 Number of Boxes: NA

1.4. Cycle selection:

Lumenis	Cycle01	Cycle03
	X	

Number of Runs: 1 Volume m3: 1,03

1.5. Data of Arrival: 2018.11.30 Time: 11:00

1.6. Temperature measurements of Incoming goods:

1.6.1. Min/Max Temperature of incoming goods °C: Min: 15 Max: 15

1.6.2. Set Acclimatization time for incoming 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:	301120180101
Boxes per Batch:	NA	Cycle Number:	9113010

2.1.2. Process Parameters:

Parameter	Requirement	Actual	Pass/Fail
Preconditioning Hold	4-12h	11	Pass
Preconditioning Temperature	40-55°C	40	Pass
Preconditioning Relative Humidity	40-75%	46	Pass
Transfer to Sterilization Chamber	≤30min	5	Pass
Temperature of the load when entering sterilization chamber	min 35°C	40	Pass
Vacuum setpoint for Air removal	50 mBar	50	Pass
Maximum pressure increase during leak test	5 mBar	1	Pass
Nitrogen Addition	600+/-60mBar	614	Pass

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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	101	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	203	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	53	Pass
	Gass Exposure pressure 720-800mBar	756	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	504	Pass
	(Air) = 60+/-10mBar	65	Pass
	(Air) = 800+/-80mBar	800	Pass
Post exposure flushing time	45-60min	60	Pass
Release	1000+/-200mBar	814	Pass
Aeration Temperature	40-50°C	41	Pass
Aeration Time	48-0/+12h	47	Pass
ETO gas consumption	2,7-3,3kg	3,44	Pass

2.1.3. **BI placement:**

2.1.3.1. **BI's Evaluation:**

Number of PASS results:

Number of FAIL results:

Number of BI's LOT No: Exp.Date: 06.2019.

3. PROCES SUMMARY

3.1. **Number of succsefull Batches:**

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3.2. Number of succesfully processed Pallets:

1

3.3. Number of succesfully processed Boxes:

NA

3.4. Number of deviation reports:

0

Data: 2018.12.03

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.
