

STERILIZATION REPORT

No: 1/02052018



OSMUNDS STERILIZĀCIJAS CENTRS
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1. ORDER INFORMATION

1.1. Order Reg. NO.: **Ink Machines** Customer Batch id: MAR 18; APR 18; MAY 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: 1,5

1.5. Data of Arrival: 24/04/2018 Time: 11:00

1.6. Temperature measurements of Incoming goods:

1.6.1. Min/Max Temperature of incoming goods °C: Min: 16 Max: 16

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: NA
Boxes per Batch: NA Cycle Number: 1042710

2.1.2. Process Parameters:

Parameter	Requirement	Actual	Pass/Fail
Preconditioning Hold	4-12h	12	Pass
Preconditioning Temperature	40-55°C	41	Pass
Preconditioning Relative Humidity	40-75%	43	Pass
Transfer to Sterilization Chamber	≤30min	8	Pass
Temperature of the load when entering sterilization chamber	min 35°C	36	Pass
Vacuum setpoint for Air removal	50 mBar	50	Pass
Maximum pressure increase during leak test	5 mBar	4	Pass
Nitrogen Addition	600+/-60mBar	614	Pass

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Evacuation	40-60mBar	60	Pass
Set point for Humidification Pressure	50mBar	50	Pass
Steam injection time	3-10min	4	Pass
Humidity Stabilization time	30+/-3min	30	Pass
Humidity Dwell Pressure	100+/-30mBar	98	Pass
1st Nitrogen injection diff. pressure	0 mBar	0	Pass
1st ETO injection differential pressure	300+/-10mBar	301	Pass
2nd Nitrogen injection diff. pressure	200+/-30mBar	205	Pass
2nd ETO injection differential pressure	100+/-20mBar	150	Pass
Last Nitrogen injection diff. pressure	100+/-20mBar	128	Pass
Total ETO injection time	10-15min	13	Pass
Total Nitrogen injection time	20-40sec	30	Pass
Gas Dwell	Duration 240-0/+10min	180	Pass
	Temperature 50+/-5°C	52	Pass
	Gass Exposure pressure 720-800mBar	778	Pass
Time taken to evaquate the chamber	max 10min	7,5	Pass
Gas Wash (2 nitrogen, 6 Air pulsations)	(N2) = 65+/-15mBar	77	Pass
	(N2) = 500+/-50mBar	525	Pass
	(Air) = 60+/-10mBar	62	Pass
	(Air) = 800+/-80mBar	797	Pass
Post exposure flushing time	45-60min	54	Pass
Release	1000+/-200mBar	813	Pass
Aeration Temperature	40-50°C	42	Pass
Aeration Time	48-0/+12h	19	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:

Number of FAIL results:

Number of BI's

LOT No:

Exp.Data.: 06.2019.

3. PROCES SUMMARY

3.1. **Number of succsefull Batches:**

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3.2. Number of successfully processed Pallets:

1

3.3. Number of successfully processed Boxes:

NA

3.4. Number of deviation reports:

0

Data: 02/05/2018

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.
