

STERILIZATION REPORT

No: 1/23072018



OSMUNDS STERILIZĀCIJAS CENTRS
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1. ORDER INFORMATION

1.1. Order Reg. NO.: **Ink Machines** Customer Batch id: JULY 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	Cycle03
	X	

 Number of Runs: 1 Volume m3: 1,81

1.5. Data of Arrival: 19/07/2018 Time: 11:00

1.6. Temperature measurements of Incoming goods:

1.6.1. Min/Max Temperature of incoming goods °C: Min: 23 Max: 24

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: 19072018
 Boxes per Batch: 16 Cycle Number: 1071910

2.1.2. Process Parameters:

Parameter	Requirement	Actual	Pass/Fail
Preconditioning Hold	4-12h	5	Pass
Preconditioning Temperature	40-55°C	44	Pass
Preconditioning Relative Humidity	40-75%	55	Pass
Transfer to Sterilization Chamber	≤30min	4	Pass
Temperature of the load when entering sterilization chamber	min 35°C	43	Pass
Vacuum setpoint for Air removal	50 mBar	50	Pass
Maximum pressure increase during leak test	5 mBar	1	Pass
Nitrogen Addition	600+/-60mBar	609	Pass

STERILIZATION REPORT

No: 1/23072018

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	76	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	230	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	800	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	522	Pass
	(Air) = 60+/-10mBar	65	Pass
	(Air) = 800+/-80mBar	804	Pass
Post exposure flushing time	45-60min	60	Pass
Release	1000+/-200mBar	822	Pass
Aeration Temperature	40-50°C	54	Pass
Aeration Time	48-0/+12h	48	Pass
ETO gas consumption	2,7-3,3kg	3,02	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:**

STERILIZATION REPORT

No: 1/23072018

3.2. Number of successfully processed Pallets:

1

3.3. Number of successfully processed Boxes:

16

3.4. Number of deviation reports:

0

Data: 23/07/2018

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.
