

STERILIZATION REPORT

No: 1/18032019



OSMUNDS STERILIZĀCIJAS CENTRS
Siltuma ielā 4, Rīgā, LV – 1058, reģistrācijas Nr. 40003162732
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1. ORDER INFORMATION

1.1. **Order Reg. NO.:** **Ink Machines** **Customer Batch id:** January 19;March 19

1.2. **Customer Name/ID:** PO07032019

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:** 1.87

1.5. **Data of Arrival:** 12-03-19 **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 D sticker Number: 120320190101

Boxes per Batch: NA Cycle Number: 3031510

2.1.2. Process Parameters:

Parameter	Requirement	Actual	Pass/Fail
Preconditioning Hold	4-12h	9	Pass
Preconditioning Temperature	40-55°C	43	Pass
Preconditioning Relative Humidity	40-75%	45	Pass
Transfer to Sterilization Chamber	≤30min	5	Pass
Temperature of the load when entering sterilization chamber	min 35°C	45	Pass
Vacuum setpoint for Air removal	50 mBar	50	Pass
Maximum pressure increase during leak test	5 mBar	1	Pass
Nitrogen Addition	600+/-60mBar	600	Pass
Evacuation	40-60mBar	50	Pass

STERILIZATION REPORT

No: 1/18032019

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	82	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	102	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	52	Pass
	Gass Exposure pressure 720-800mBar	750	Pass
Time taken to evaquate the chamber	max 10min	7.5	Pass
Gas Wash (2 nitrogen, 6 Air pulsations)	(N2) = 65+/-15mBar	62	Pass
	(N2) = 500+/-50mBar	502	Pass
	(Air) = 60+/-10mBar	60	Pass
	(Air) = 800+/-80mBar	802	Pass
Post exposure flushing time	45-60min	60	Pass
Release	1000+/-200mBar	817	Pass
Aeration Temperature	40-50°C	45	Pass
Aeration Time	48-0/+12h	48	Pass
ETO gas consumption	≥2,7kg	3.68	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. Dat: 31.12.2019.

3. PROCES SUMMARY

3.1. <u>Number of succsefull Batches:</u>	1
3.2. <u>Number of succsesfully processed Pallets:</u>	1
3.3. <u>Number of succsesfully processed Boxes:</u>	NA
3.4. <u>Number of deviation reports:</u>	0

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Data: 18-03-19

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.
