

STERILIZATION REPORT

No: 1/21102019



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: April - 19/October - 10

1.2. Customer Name/ID: **PO 2019-10-11**

1.3. Product: **NEO cartritdges** Number of Pallets: **1** Number of Boxes: **12**

1.4. Cycle selection:

Lumenis	Cycle01	Cycle03
	X	

 Number of Runs: **1** Volume m3: **1.498**

1.5. Data of Arrival: **17-10-19** Time: **14:00**

1.6. Temperature measurements of Incoming goods:

1.6.1. Min/Max Temperature of incoming goods °C: Min: **14** Max: **14**

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:	171020190201
Boxes per Batch:	12	Cycle Number:	1101810

2.1.2. Process Parameters:

Parameter	Requirement	Actual	Pass/Fail
Preconditioning Hold	4-12h	12	Pass
Preconditioning Temperature	40-55°C	44	Pass
Preconditioning Relative Humidity	40-75%	55	Pass
Transfer to Sterilization Chamber	≤30min	7	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	602	Pass
Evacuation	40-60mBar	50	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	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	201	Pass
2nd ETO injection differential pressure	100+/-20mBar	100	Pass

STERILIZATION REPORT

No: 1/21102019

Last Nitrogen injection diff. pressure	100+/-20mBar	100	Pass
Total ETO injection time	10-15min	8	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	738	Pass
Time taken to evaquate the chamber	max 10min	10	Pass
Gas Wash (2 nitrogen, 6 Air pulsations)	(N2) = 65+/-15mBar	60	Pass
	(N2) = 500+/-50mBar	502	Pass
	(Air) = 60+/-10mBar	60	Pass
	(Air) = 800+/-80mBar	799	Pass
Post exposure flushing time	45-60min	60	Pass
Release	1000+/-200mBar	816	Pass
Aeration Temperature	40-50°C	43	Pass
Aeration Time	48-0/+12h	50	Pass
ETO gas consumption	≥2,7kg	3.79	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. Number of succsefull Batches:	1
3.2. Number of succesfully processed Pallets:	1
3.3. Number of succesfully processed Boxes:	NA
3.4. Number of deviation reports:	0

Data: 21-10-19
 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.