



Sterilization report Nr. 1/17.06.2022.

Customer/order information

| | |
|---------------------------|-------------------------------|
| Customer | Specialmekaniska (InkMachine) |
| Order no. | 1/103062022 |
| Incoming date | 10.06.2022. |
| Customers reference | Batch June -22 |
| Product | Ink cartridges |
| Sterilization cycle name | Cycle 01 |
| Sterilization date | 15.06.2022. |
| Sterilization batch/cycle | 00033061510 |
| Load (volume/weight) | 3,72 m3 26 boxes 750kg |

Sterilization cycle review

| PHASE | PARAMETER | UNIT | | Minimum | Actual | Maximum | Status |
|------------------------------------------|---------------------------|-------|--|---------|--------|---------|-----------|
| | | | | | | | PASS/FAIL |
| Acclimatization (Incoming goods area) | Temperature | °C | | 15 | 15 | NA | PASS |
| | | | | | | | |
| Preconditioning | Temperature | °C | | 40 | 48 | 50 | PASS |
| | Relative humidity | %RH | | 45 | 55 | 75 | PASS |
| | Time | h | | 12 | 12 | 14 | PASS |
| | | | | | | | |
| Transfer time | Time | min | | NA | 7 | 18 | PASS |
| | | | | | | | |
| | Evacuation pressure | mbarA | | 45 | 53 | 55 | PASS |
| | Stabilization time | min | | 4 | 5 | 6 | PASS |
| | Leak test | min | | 2 | 2 | 2 | PASS |
| | Leak rate | mbar | | NA | 1 | 5 | PASS |
| | Nitrogene pulsation | mbar | | 550 | 612 | 650 | PASS |
| | | | | | | | |
| Humidification/ Steam conditioning | Humidification Δp | mbar | | 27 | 30 | 33 | PASS |
| | Steam dwell time | min | | 27 | 30 | 33 | PASS |
| | Steam dwell end pressure | mbarA | | 62 | 73 | 88 | PASS |
| | Humidity of the chamber | Rh% | | 30 | 76 | 80 | PASS |
| | | | | | | | |
| EO exposure | EO injection | mbarA | | 385 | 400 | 415 | PASS |
| | | min | | NA | 8 | NA | PASS |
| | | kg | | 2,7 | 3,73 | NA | PAS* |
| | Gas injection temperature | °C | | 15 | 39 | NA | PASS |



| | | | | | | | |
|--------------------------|------------------------------------------------|------|--|-----|-----|-----|------|
| | EO concentration at end of gas injection phase | mg/L | | 700 | 700 | 800 | PASS |
| | EO dwell time | min | | 180 | 180 | 190 | PASS |
| | Satisfactory of gas circulation | Y/N | | NA | Y | NA | PASS |
| | EO dwell temperature | °C | | 52 | 53 | 58 | PASS |
| | Evacuation time | min | | NA | 10 | NA | PASS |
| | | | | | | | |
| Nitrogene/Air wash phase | Number of wash cycles Nitrogen | | | 2 | 2 | 2 | PASS |
| | Nitrogen Rinsing vacuum | mbar | | 55 | 60 | 65 | PASS |
| | Nitrogene rinsing pressure | mbar | | 450 | 516 | 550 | PASS |
| | Number of First Air rinsing steps | | | 5 | 5 | 5 | PASS |
| | Air wash 1st: rinsing vacuum | mbar | | 55 | 60 | 65 | PASS |
| | Air wash 1st: rinsing pressure | mbar | | 750 | 806 | 850 | PASS |
| | Time during flushing | min | | NA | 55 | NA | PASS |
| | | | | | | | |
| Degassing | Temperature | °C | | 35 | 51 | 55 | PASS |
| | Time | h | | 24 | 30 | 36 | PASS |

| | |
|---------------------------------------|-------------|
| Biological indicator (Bac.Atrophaeus) | Etigam |
| Number of BI | 4 |
| Indicator LOT | 5260 |
| Test time | 48h |
| Result (PASS/FAIL) | Pass |
| End date of control | 17.06.2022. |

Conclusion

The EO sterilized batch, perform according to ISO-11135:2104 standard complied with Osmunds approved cycle specifications for optical fiber product.

Date: 17.06.2022.

Cycle approved

R. Baranovskis
Managing director of sterilization centre