Sterilization certified in line with

**EN ISO 13485:2016 / EN ISO 11135:2014**

MPI

**MEDICOPLAST**
International GmbH

# Confirmation of Sterilization

Method: VA_S_1

| | |
|---|---|
| Sterilization date: | 2021-11-06 |
| Sterilization lot: | 19290 |
| Customer: | MT.DERM GmbH |
| Your requisition no.: | 03112021<br>GB48=21-EB3236 GB22=21-EB3237 GB21=21-EB3238<br>GB11=21-EB3239 GB26=21-EB3240 GB24=21-EB3241<br>GB40=21-EB3242 GB5=21-EB3243 GB42=21-EB3244<br>GB9=21-EB3245 |
| Our delivery note: | 257925 from 2021-11-11 |
| Item: | 9900031<br>Sterilisation Pal. MP01 1d NK<br>Pr.70 |
| Quantity: | 10 Pal. |

| | | Nominal values | Actual values |
|---|---|---|---|
| **Incoming time:** | | min. 12 h | **32 h** |
| **Preconditioning** | | | |
| Dwell: | | min. 16 h | **21 h** |
| Conditions: | | 35-45°C 50-80% rel.humidity | **35-45°C 50-80% rel.humidity** |
| **Sterilization** | | | |
| Cycle: | **MP1** | | |
| Temperature: | | 40 ±3 °C | **40 °C** |
| Prevacuum: | | 120 ±10 mbar abs | **119 mbar abs** |
| Humidity: | | 50-80% rel.humidity | **77,1% rel.humidity** |
| Dwell time: | | 3 h | **3 h** |
| EO mass: | | 16-32 kg | **26 kg** |
| Air washes: | | min. 3 | **3** |
| **Aeration** | | | |
| Dwell: | | min. 1 Days | **4,5 Days** |
| Condition: | | 35-45 °C | **35-45 °C** |

**Remarks:** The evaluation from the BI's is in process.

The physical parameters were in accordance to the specifications.

No growth was observed for the microbiological inprocess control with biological indicators (Bacillus atrophaeus, 3M Attest).
The sterilization was conducted in line with the customer validation parameter.

**Approval**

Signature QS: _____ Date: 11. 11. 21