

Sterilization certified in line with

EN ISO 13485:2016 / EN ISO 11135:2014



MEDICOPLAST
International GmbH

Confirmation of Sterilization

Method: VA_S_1

| | |
|-----------------------|--|
| Sterilization date: | 2020-10-20 |
| Sterilization lot: | 18543 |
| Customer: | MT.DERM GmbH |
| Your requisition no.: | 14102020 GB2=20-EB2997 GB4=20-EB2923 GB11=20-EB2912 GB16=20-EB2971 GB17=20-EB2976 GB21=20-EB2970 |
| Our delivery note: | 252661 from 2020-10-22 |
| Item: | 9900031 Sterilisation Pal. MP01 1d NK Pr.70 |
| Quantity: | 6 Pal. |

| | Nominal values | Actual values |
|------------------------|---|-----------------------------|
| <u>Incoming time:</u> | (April to October not required) | |
| <u>Preconditioning</u> | | |
| Dwell: | min. 16 h | 30,5 h |
| Conditions: | 35-45°C 50-80% rel.humidity | 35-45°C 50-80% rel.humidity |
| <u>Sterilization</u> | | |
| Cycle: | MP1 | |
| Temperature: | 40 ±3 °C | 40 °C |
| Prevacuum: | 120 ±10 mbar abs | 125 mbar abs |
| Humidity: | 50-80% rel.humidity | 70,2% rel.humidity |
| Dwell time: | 3 h | 3 h |
| EO mass: | 16-32 kg | 28 kg |
| Air washes: | min. 3 | 3 |
| <u>Aeration</u> | | |
| Dwell: | min. 1 Days | 1 Days |
| Condition: | 35-45 °C | 35-45 °C |
| <u>Remarks:</u> | 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: 23.10.2020

Freigabe
23.10.2020
Verysoft Cert.
CD