

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:	2020-11-10
Sterilization lot:	18580
Customer:	MT.DERM GmbH
Your requisition no.:	04112020 GB12=20-EB3327, GB5=20-EB3328, GB14=20-EB3329, GB3=20-EB3309, GB43=20-EB3309
Our delivery note:	252950 from 2020-11-12
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	5 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	min. 12 h	100 h
<u>Preconditioning</u>		
Dwell:	min. 16 h	18,25 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
<u>Sterilization</u>		
Cycle:	<u>MP1</u>	
Temperature:	40 ±3 °C	40 °C
Prevacuum:	120 ±10 mbar abs	123 mbar abs
Humidity:	50-80% rel.humidity	62,1% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	26 kg
Air washes:	min. 3	3
<u>Aeration</u>		
Dwell:	min. 1 Days	1,5 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: X Date: 12/11/20

Freigegeben
16.11.2020
Goscinięc
OK GEPRÜFT