

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:	2019-11-18
Sterilization lot:	17897
Customer:	MT.Derm GmbH
Your delivery note:	19-EB4644,19-EB4670,
Your requisition no.:	19-EB4681,19-EB4689,19-EB4692,19-EB4693,19-EB4717,
Our delivery note:	248016 from 2019-11-21
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	2 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	min. 12 h	58,5 h
<u>Preconditioning</u>		
Dwell:	min. 16 h	47,25 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	39,5 °C
Prevacuum:	120 ±10 mbar abs	129 mbar abs
Humidity:	50-80% rel.humidity	51,3% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	27 kg
Air washes:	min. 3	3
<u>Aeration</u>		
Dwell:	min. 1 Days	2 Days
Condition:	35-45 °C	35-45 °C
<u>Remarks:</u>		

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: 21.11.19

*Freigegeben
GOSCHNEE
22.11.19
OK GEPRÜFT*