

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: 2019-12-16  
Sterilization lot: 17958

Customer: MT.Derm GmbH

Your delivery note: 19-EB5059,19-EB5079,  
Your requisition no.: 19-EB5081,19-EB5109,19-EB5110,19-EB5111,19-EB5125,  
19-EB5131,19-EB5132,19-EB5151,19-EB5152,19-EB5153,  
19-EB5161,19-EB5168

Our delivery note: 248491 from 2019-12-18

Item: 9900031  
Sterilisation Pal. MP01 1d NK  
Pr.70

Quantity: 10 Pal.

	Nominal values	Actual values
<b>Incoming time:</b>	min. 12 h	28,5 h
<b>Preconditioning</b>		
Dwell:	min. 16 h	76,5 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
<b>Sterilization</b>		
Cycle:	<u>MP1</u>	
Temperature:	40 ±3 °C	40 °C
Prevacuum:	120 ±10 mbar abs	124 mbar abs
Humidity:	50-80% rel.humidity	63,2% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	25,5 kg
Air washes:	min. 3	3
<b>Aeration</b>		
Dwell:	min. 1 Days	2 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: \_\_\_\_\_

Freigegeben  
Gossmic  
20.12.19  
OK GEPRÜFT