

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:	2019-08-06
Sterilization lot:	17685
Customer:	MT.Derm GmbH
Your delivery note:	19-EB3104, 19-EB3105,
Your requisition no.:	19-EB3107, 19-EB3107, 19-EB3106, 19-EB3101, 19-EB3100, 19-EB3085, 19-EB3045, 19-EB3043, 19-EB3041, 19-EB3037, 19-EB3115
Our delivery note:	246444 from 2019-08-08
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	10 Pal.

	Nominal values	Actual values
<b>Incoming time:</b>	(April to October not required)	
<b>Preconditioning</b>		
Dwell:	min. 16 h	24,5 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
<b>Sterilization</b>		
Cycle:	<b>MP1</b>	
Temperature:	40 ± 3 °C	40 °C
Prevacuum:	120 ± 10 mbar abs	125 mbar abs
Humidity:	50-80% rel.humidity	56,1% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	26 kg
Air washes:	min. 3	3
<b>Aeration</b>		
Dwell:	min. 1 Days	1 Days
Condition:	35-45 °C	35-45 °C
<b>Remarks:</b>	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: 8.8.19

OK  
CERTIFIED  
08.08.2019  
