

Sterilization certified in line with



**MEDICOPLAST**  
international GmbH

EN ISO 13485:2016 / EN ISO 11135:2014

## Confirmation of Sterilization

Method: VA\_S\_1

Sterilization date: 2019-11-05  
Sterilization lot: 17868

Customer: MT.Derm GmbH

Your delivery note: 19-EB4528,19-EB4525,  
Your requisition no.: 19-EB4524,19-EB4522,19-EB4512,19-EB4511,19-EB4495,  
19-EB4487,19-EB4464,19-EB4466,19-EB4467,  
19-EB4443,19-EB4523

Our delivery note: 247772 from 2019-11-07

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

Quantity: 10 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	min. 12 h	0 h
<u>Preconditioning</u>		
Dwell:	min. 16 h	23 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	39,5 °C
Prevacuum:	120 ±10 mbar abs	126 mbar abs
Humidity:	50-80% rel.humidity	55,0% 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 Days
Condition:	35-45 °C	35-45 °C

Remarks: No incoming time needed, because incoming was before November.  
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: S Date: 7.11.19

*Freigeben  
Goschnic  
08.11.19  
OK GEPRÜFT*