

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: 2019-10-29
Sterilization lot: 17854

Customer: MT.Derm GmbH

Your delivery note: 19-EB4341,19-EB4344,
Your requisition no.: 19-EB4350,19-EB4355,19-EB4362,19-EB4371,
19-EB4381,19-EB4396,19-EB4408,19-EB4416,
19-EB4418,19-EB4422,19-EB4431

Our delivery note: 247675 from 2019-10-31

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

Quantity: 10 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	(April to October not required)	
<u>Preconditioning</u>		
Dwell:	min. 16 h	35,25 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	122 mbar abs
Humidity:	50-80% rel.humidity	56,7% 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: 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: 37.10.19

Freigegeben
OK **GEPRÜFT**
04.10.19
[Signature]