

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:	2021-04-20
Sterilization lot:	18868
Customer:	MT.DERM GmbH
Your requisition no.:	14042021 GB40=21-EB0985, GB18=21-EB0986 GB27=21-EB0987, GB28=21-EB0988, GB1=21-EB0989 GB6=21-EB0990 und GB22=21-EB0991
Our delivery note:	255115 from 2021-04-22
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	7 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	(April to October not required)	
<u>Preconditioning</u>		
Dwell:	min. 16 h	26,5 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	41 °C
Prevacuum:	120 ±10 mbar abs	123 mbar abs
Humidity:	50-80% rel.humidity	63,8% 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 BfS 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: 22/4/2021