

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: 2020-02-04
Sterilization lot: 18025

Customer: MT.Derm GmbH

Your delivery note: 20-EB0103, 20-EB0171
Your requisition no.: 20-EB0216, 20-EB0227, 20-EB0228, 20-EB0324,
20-EB0362, 20-EB0363, 20-EB0371, 20-EB0373, 20-EB0381,
20-EB0387, 20-EB0419,
20-EB0427 20-EB0428

Our delivery note: 249047 from 2020-02-06

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

Quantity: 10 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	min. 12 h	106 h
<u>Preconditioning</u>		
Dwell:	min. 16 h	23,5 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	39,5 °C
Prevacuum:	120 ±10 mbar abs	123 mbar abs
Humidity:	50-80% rel.humidity	64,2% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	26,5 kg
Air washes:	min. 3	3
<u>Aeration</u>		
Dwell:	min. 1 Days	1 Days
Condition:	35-45 °C	35-45 °C
<u>Remarks:</u>	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: 6/21/20

*Freigegeben
GOSCHWIEC
07.02.2020
OK GEPRÜFT*