

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: 2020-11-03
Sterilization lot: 18566

Customer: MT.DERM GmbH

Your requisition no.: 28102020
GB18=20-EB3227,GB10=20-EB3233,GB11=20-EB3240,GB4=20-EB3241

Our delivery note: 252863 from 2020-11-05

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

Quantity: 4 Pal.

	Nominal values	Actual values
Incoming time:	min. 12 h	0 h
Preconditioning		
Dwell:	min. 16 h	23,5 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
Sterilization		
Cycle:	MP1	
Temperature:	40 ±3 °C	40 °C
Prevacuum:	120 ±10 mbar abs	124 mbar abs
Humidity:	50-80% rel.humidity	63,2% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	27,5 kg
Air washes:	min. 3	3
Aeration		
Dwell:	min. 1 Days	1,5 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: _____ Date: 5.12.20

Freigabe
06.11.2020
Vig. Control Center
C. G.