

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:	2020-08-10
Sterilization lot:	18411
Customer:	MT.Derm GmbH
Your delivery note:	20-EB2124,20-EB2168,
Your requisition no.:	20-EB2170,20-EB2173,20-EB2177,20-EB2178,20-EB2181
Our delivery note:	251696 from 2020-08-13
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	7 Pal.

	Nominal values	Actual values
Incoming time:	(April to October not required)	
Preconditioning		
Dwell:	min. 16 h	69,5 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	69,8% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	25,5 kg
Air washes:	min. 3	3
Aeration		
Dwell:	min. 1 Days	2 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: 73.8.20