Sterilization certified in line with

EN ISO 13485:2016 / EN ISO 11135:2014

MPI

MEDICOPLAST
International GmbH

Confirmation of Sterilization

Method: VA_S_1

Sterilization date:	2021-08-23
Sterilization lot:	19134
Customer:	MT.DERM GmbH
Your delivery note:	18082021
Your requisition no.:	GB27=21-EB2424,GB3=21-EB2425 GB19=21-EB2426 GB42=21-EB2427 GB20=21-EB2428 GB4=21-EB2429 GB6=21-EB2430 GB41=21-EB2431 GB9=21-EB2432
Our delivery note:	256842 from 2021-08-26
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	9 Pal.

		Nominal values	Actual values
Incoming time:		(April to October not required)	
Preconditioning			
Dwell:		min. 16 h	**48,25 h**
Conditions:		35-45°C 50-80% rel.humidity	**35-45°C 50-80% rel.humidity**
Sterilization			
Cycle:	**MP1**		
Temperature:		40 ±3 °C	**40,5 °C**
Prevacuum:		120 ±10 mbar abs	**121 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	**2,5 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: 26.8.21