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:	2019-10-14
Sterilization lot:	17819
Customer:	MT.Derm GmbH
Your delivery note:	19-EB3996,19-EB4003
Your requisition no.:	19-EB4012,19-EB4053,19-EB4055
Our delivery note:	247445 from 2019-10-16
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	6 Pal.

	Nominal values	Actual values
Incoming time:	(April to October not required)	
Preconditioning		
Dwell:	min. 16 h	**76 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	**57,6% rel.humidity**
Dwell time:	3 h	**3 h**
EO mass:	16-32 kg	**26 kg**
Air washes:	min. 3	**3**
Aeration		
Dwell:	min. 1 Days	**2 Days**
Condition:	35-45 °C	**35-45 °C**

Remarks:

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: 17.10.19

Freigegeben
18.10.19
Gosciniec

OK GEPRÜFT