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:	2020-11-18
Sterilization lot:	18599
Customer:	MT.DERM GmbH
Your requisition no.:	11112020 GB18=20-EB3386,GB30=20-EB3406,GB10=20-EB3407,GB11=20-EB3414, GB8=20-EB3415,GB4=20-EB3416
Our delivery note:	253088 from 2020-11-20
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	6 Pal.

		Nominal values	Actual values
Incoming time:		min. 12 h	**127 h**
Preconditioning			
Dwell:		min. 16 h	**23,75 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	**125 mbar abs**
Humidity:		50-80% rel.humidity	**70,5% 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	**1,5 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.

Freigegeben
23.11.2020
Gosciniec

Approval

Signature QS: _____ Date: 20/11/20

OK GEPRÜFT