

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: 2020-10-12
Sterilization lot: 18525
Customer: MT.DERM GmbH
Your requisition no.: 23092020
GB18=20-EB2869 GB8=20-EB2890 GB22=20-EB2891
GB5=20-EB2891
Our delivery note: 252570 from 2020-10-15
Item: 9900031
Sterilisation Pal. MP01 1d NK
Pr.70
Quantity: 4 Pal.

	Nominal values	Actual values
Incoming time:	(April to October not required)	
Preconditioning		
Dwell:	min. 16 h	73,75 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
Sterilization		
Cycle:	<u>MP1</u>	
Temperature:	40 ±3 °C	40 °C
Prevacuum:	120 ±10 mbar abs	125 mbar abs
Humidity:	50-80% rel.humidity	64,6% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	25 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: 15.10.20

Freigegeben
Goschke
16.10.2020
OK **GEPRÜFT**
