

Sterilization certified in line with

DIN EN ISO 13485:2012 / EN ISO 11135-1:2014



MEDICOPLAST
International GmbH

Confirmation of Sterilization

Method: VA 7-5-1-6

Sterilization date:	2019-03-05
Sterilization lot:	17336
Customer:	MT.Derm GmbH
Your delivery note:	19-EB0857,19-EB0873,
Your requisition no.:	19-EB0913,19-EB0940,19-EB0950, 19-EB0952,19-EB0955,19-EB0826
Our delivery note:	244337 from 2019-03-07
Item:	9900031 Sterilisation Pal. MP01 1d NK Pr.70
Quantity:	8 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	min. 12 h	106,25 h
<u>Preconditioning</u>		
Dwell:		
Conditions:	35-45°C 50-80% rel.humidity	25,5 h 35-45°C 50-80% rel.humidity
<u>Sterilization</u>		
Cycle:	MP1	
Temperature:	40 ±3 °C	40 °C
Prevacuum:	120 ±10 mbar abs	128 mbar abs
Humidity:	50-80% rel.humidity	61,2% rel.humidity
Dwell time:	3 h	3 h
EO concentration (calc.):	1.000±50 mg/l	1.000 mg/l
Air washes:	min. 3	3
<u>Aeration</u>		
Dwell:		
Condition:	min. 1 Days 35-45 °C	1 Days 35-45 °C
<u>Remarks:</u>	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: Y Date: 11.03.19

11.03.19
Fokal geprüft
GEPRÜFT
Goscinięc