

Sterilization certified in line with

EN ISO 13485:2016 / EN ISO 11135:2014



**MEDICOPLAST**  
International GmbH

## Confirmation of Sterilization

Method: VA\_S\_1

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Sterilization date: 2020-03-13  
Sterilization lot: 18110

Customer: MT.Derm GmbH

Your delivery note: 20-EB1102, 20-EB1103  
Your requisition no.: 20-EB1148, 20-EB1162, 20-EB1165, 20-EB1175,  
20-EB1190, 20-EB1216, 20-EB1217, 20-EB1220, 20-EB1232

Our delivery note: 249712 from 2020-03-19

Item: 9900031  
Sterilisation Pal. MP01 1d NK  
Pr.70

Quantity: 10 Pal.

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	Nominal values	Actual values
<u>Incoming time:</u>	min. 12 h	12 h
<u>Preconditioning</u>		
Dwell:	min. 16 h	24,75 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
<u>Sterilization</u>		
Cycle:	MP1	
Temperature:	40 ±3 °C	40 °C
Prevacuum:	120 ±10 mbar abs	124 mbar abs
Humidity:	50-80% rel.humidity	50-80% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	26 kg
Air washes:	min. 3	3
<u>Aeration</u>		
Dwell:	min. 1 Days	5 Days
Condition:	35-45 °C	35-45 °C

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Remarks: The evaluation from the BI's is in process.

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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: J Date: 13/3/20

*Freigegeben  
Goscwiec  
20.03.2020  
OK GEPRÜFT*