

Sterilization certified in line with



**MEDICOPLAST**  
International GmbH

EN ISO 13485:2016 / EN ISO 11135:2014

## Confirmation of Sterilization

Method: VA\_S\_1

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Sterilization date: 2020-09-08  
Sterilization lot: 18462  
  
Customer: MT.Derm GmbH  
  
Your requisition no.: 02092020  
GB21=20-EB2453 GB15=20-EB2454 GB20=20-EB2479  
GB17=20-EB2480 GB23=20-EB2489 GB02=20-EB2490  
GB07=20-EB2502 GB06=20-EB2504 GB24=20-EB2506  
GB25=20-EB2509  
  
Our delivery note: 252033 from 2020-09-10  
  
Item: 9900031  
Sterilisation Pal. MP01 1d NK  
Pr.70  
  
Quantity: 10 Pal.

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	Nominal values	Actual values
<u>Incoming time:</u>	(April to October not required)	
<u>Preconditioning</u>		
Dwell:	min. 16 h	29,5 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	40,5 °C
Prevacuum:	120 ±10 mbar abs	123 mbar abs
Humidity:	50-80% rel.humidity	67,8% 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	1 Days
Condition:	35-45 °C	35-45 °C
<u>Remarks:</u>	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: \_\_\_\_\_ Date: 10/09/2020

*Freigegeben  
Gosciniak*  
11.09.2020  
**OK GEPRÜFT**  
*[Signature]*