

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: 2022-08-01  
Sterilization lot: 19834  
  
Customer: MT.DERM GmbH  
  
Your requisition no.: 27072022  
GB6=22-EB2279 GB99=22-EB2280 GB18=22-EB2281 GB10=22-EB2282  
GB8=22-EB2283 GB9=22-EB2284 GB14=22-EB2285 GB42=22-EB2286  
GB4=22-EB2287 GB40=22-EB2288  
  
Our delivery note: 261341 from 2022-08-04  
  
Item: 9900031  
Sterilisation Pal. MP01 1d NK  
Pr.70  
  
Quantity: 10 Pal.

	Nominal values	Actual values
<b>Incoming time:</b>	(April to October not required)	
<b>Preconditioning</b>		
Dwell:	min. 16 h	45,25 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
<b>Sterilization</b>		
Cycle:	MP1	
Temperature:	40 ±3 °C	40,6 °C
Prevacuum:	120 ±10 mbar abs	124 mbar abs
Humidity:	50-80% rel.humidity	55,7% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	26,5 kg
Air washes:	min. 3	3
<b>Aeration</b>		
Dwell:	min. 1 Days	2,5 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.

**FREIGABE**

09. AUG. 2022

*N. Popovskaa*  
*R.*

**Approval**

Signature QS: \_\_\_\_\_

Date: 04.08.2022

01.08.22  
12:13:41

CHARGEN-NR. : 19834  
GERÄTE-NR. : 1895  
BEDIENER : 2  
PROGRAMM-NR: 70  
ANF.-DRUCK : 600  
END-DRUCK : 500  
TEMPERATUR : 40

FREIGABE  
09. AUG. 2022  
*N. Paganeksha*  
*GR*

