

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: 2022-01-15  
Sterilization lot: 19414  
Customer: MT.DERM GmbH  
Your requisition no.: 120122  
43 22-EB0096,04 22-EB0097,13 22-EB0098,23 22-EB0099  
28 22-EB0104  
Our delivery note: 258743 from 2022-01-20  
Item: 9900031  
Sterilisation Pal. MP01 1d NK  
Pr.70  
Quantity: 5 Pal.

	Nominal values	Actual values
<b>Incoming time:</b>	min. 12 h	<b>28,75 h</b>
<b>Preconditioning</b>		
Dwell:	min. 16 h	<b>22,75 h</b>
Conditions:	35-45°C 50-80% rel.humidity	<b>35-45°C 50-80% rel.humidity</b>
<b>Sterilization</b>		
Cycle:	<b>MP1</b>	
Temperature:	40 ±3 °C	<b>39,8 °C</b>
Prevacuum:	120 ±10 mbar abs	<b>119 mbar abs</b>
Humidity:	50-80% rel.humidity	<b>67,4% rel.humidity</b>
Dwell time:	3 h	<b>3 h</b>
EO mass:	16-32 kg	<b>26 kg</b>
Air washes:	min. 3	<b>3</b>
<b>Aeration</b>		
Dwell:	min. 1 Days	<b>4,5 Days</b>
Condition:	35-45 °C	<b>35-45 °C</b>

**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: 20.01.2022

**FREIGABE**

24. JAN. 2022

*Natalia Rogowelska*  
*R*

15.01.22 CHARGEN-NR.: 19414  
11:27:59 GERÄTE-NR.: 1895  
BEDIENER : 2  
PROGRAMM-NR: 70  
ANF.-DRUCK : 600  
END-DRUCK : 500  
TEMPERATUR : 40

FREIGABE  
24. JAN. 2022  
*N. Proquelski*  
*Ru*

