

Sterilization certified in line with

EN ISO 13485:2016 / EN ISO 11135:2014



Confirmation of Sterilization

Method: VA_S_1

Sterilization date: 2020-09-15
Sterilization lot: 18476

Customer: MT.DERM GmbH

Your requisition no.: 09092020
GB4=20-EB2554 GB5=20-EB2546 GB8=20-EB2529
GB12=20-EB2563 GB13=20-EB2595 GB16=20-EB2597
GB18=20-EB2599 GB22=20-EB2566 GB26=20-EB2531
GB27=20-EB2593

Our delivery note: 252154 from 2020-09-17

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

Quantity: 10 Pal.

	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 °C
Prevacuum:	120 ±10 mbar abs	123 mbar abs
Humidity:	50-80% rel.humidity	70,7% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	25,5 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.	

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: 17.09.2020

*Freigegeben
Goscuniec*
18.09.2020
OK 