

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: 2021-04-19
Sterilization lot: 18065

Customer: MT.DERM GmbH

Your requisition no.: 14042021
GB13=21-EB0978, GB2=21-EB0979, GB16=21-EB0980,
GB8= 21-EB0981, GB23=21-EB0982 GB19=21-EB0983,
GB4=21-EB0984

Our delivery note: 255115 from 2021-04-22

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

Quantity: 7 Pal.

	Nominal values	Actual values
<u>Incoming time:</u>	(April to October not required)	
<u>Preconditioning</u>		
Dwell:	min. 16 h	32 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	39,5 °C
Prevacuum:	120 ±10 mbar abs	123 mbar abs
Humidity:	50-80% rel.humidity	66,5% 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	2 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 atropheus, 3M Attest).

The sterilization was conducted in line with the customer validation parameter.

Approval

Signature QS:

Date: 22/04/21

22 APR. 2021
frigobag
Vogelstet
Wolff