

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: 2020-02-10
Sterilization lot: 18038
Customer: MT.Derm GmbH
Your delivery note: 20-EB0450, 20-EB0451
Your requisition no.: 20-EB0452, 20-EB0477, 20-EB0482, 20-EB0498,
20-EB0503, 20-EB0504, 20-EB0505, 20-EB0531, 20-EB0536,
20-EB0537, 20-EB0538, 20-EB0539, 20-EB0540
Our delivery note: 249149 from 2020-02-13
Item: 9900031
Sterilisation Pal. MP01 1d NK
Pr.70
Quantity: 5 Pal.

	Nominal values	Actual values
Incoming time:	min. 12 h	77 h
Preconditioning		
Dwell:	min. 16 h	26,25 h
Conditions:	35-45°C 50-80% rel.humidity	35-45°C 50-80% rel.humidity
Sterilization		
Cycle:	MP1	
Temperature:	40 ±3 °C	40 °C
Prevacuum:	120 ±10 mbar abs	126 mbar abs
Humidity:	50-80% rel.humidity	61,8% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	26,5 kg
Air washes:	min. 3	3
Aeration		
Dwell:	min. 1 Days	2 Days
Condition:	35-45 °C	35-45 °C

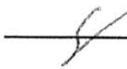
Remarks:

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: 13.02.20

Freigegeben
Goschew
14.02.2020
OK 