

Sterilization certified in line with

EN ISO 13485:2016 / EN ISO 11135:2014



Confirmation of Sterilization

Method: VA_S_1

Sterilization date: 2020-03-16
Sterilization lot: 18113

Customer: MT.Derm GmbH

Your delivery note: 20-EB1102, 20-EB1103
Your requisition no.: 20-EB1148, 20-EB1162, 20-EB1165, 20-EB1175,
20-EB1190, 20-EB1216, 20-EB1217, 20-EB1220, 20-EB1232

Our delivery note: 249712 from 2020-03-19

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

Quantity: 1 Pal.

	Nominal values	Actual values
Incoming time:	min. 12 h	52 h
Preconditioning		
Dwell:	min. 16 h	53,25 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	124 mbar abs
Humidity:	50-80% rel.humidity	60,7% rel.humidity
Dwell time:	3 h	3 h
EO mass:	16-32 kg	27 kg
Air washes:	min. 3	3
Aeration		
Dwell:	min. 1 Days	2 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.

Approval

Signature QS:  Date: 18.03.20

*Freigegeben
GOSURIEC
20.03.2020
OK GEPRÜFT*