EU Certificate

for the assessment of the technical documentation

according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter II

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

PolyMedics Innovations GmbH

Single Registration Number (SRN): DE-MF-000006353
Am Hegelesberg 1, 73230 Kirchheim unter Teck, Germany

that the technical documentation of the product(s) described in the annex complies with the provisions of the Medical Device Directive (EU) 2017/745. The certificate is based on the results of the assessment of the technical documentation according to the Medical Devices Regulation (EU) 2017/745 Annex IX Chapter II, which are recorded in the report referred to in the annex.

Product: Suprathel, Suprathel 250

EU Certificate no.: 51488-61-A1-00

Certificate valid from: 2024-05-21
Certificate valid to: 2027-12-20

Previous certificate no. 51488-61-A0, issued on 2023-02-28.

Digitally signed by Markus RAINER Kopf
Date: 2024-05-28 14:14:34+02:00

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

DEKRA Certification GmbH, Stuttgart 2024-05-28
Notified Body ID number: 0124

Annex to the EU Certificate no. 51488-61-A1-00

Report Number: 51488-TD1-01 / 51488-CN23-01 / 51488-CN24-01

Product: Suprathel, Suprathel 250

Basis-UDI-DI: 426018402AAA0000001PQ

Risk Classification: Class III

Intended Use:

Suprathel is an absorbable, microporous membrane and an alloplastic skin substitute for the treatment of epidermal and dermal wounds.

Technical Data:

Suprathel 50 – 150 µm	Size [cm]	Item number
	5 x 5	110505-MDR 150505-MDR
	9 x 10	110910-MDR 150910-MDR
	18 x 10	111810-MDR 151810-MDR
	18 x 23	111823-MDR 151823-MDR
	Hand size	12H001-MDR
	Face mask	11F001-MDR

Suprathel 250 180 – 320 µm	Size [cm]	Item number
	5 x 5	110505-250-MDR 150505-250-MDR
	9 x 10	110910-250-MDR 150910-250-MDR
	18 x 10	111810-250-MDR 151810-250-MDR
	18 x 23	111823-250-MDR 151823-250-MDR

Remark: For the placing on the market of the product(s) referred to above, an additional EU certificate for the assessment of the quality management system in accordance with Annex IX Chapter I is required.

Change to previous certificate: Change of address of the legal manufacturer.

EU Certificate

for the assessment of the quality management system

according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the manufacturer

PolyMedics Innovations GmbH

Single Registration Number (SRN): DE-MF-000006353
Am Hegelesberg 1, 73230 Kirchheim unter Teck, Germany

applies a quality management system according to Annex IX Chapter I of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo51488-00 and is only valid in conjunction with the successful completion of the annual surveillance audits

EU Certificate no.: 51488-60-01-00

Certificate valid from: 2024-05-21
Certificate valid to: 2026-12-21

Previous certificate no. 51488-60-00, issued on 2022-12-21

Digitally signed by Markus RAINER Kopf
Date: 2024-05-23 18:14:03+02:00

DEKRA Certification GmbH, Stuttgart 2024-05-23
Notified Body ID number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

Annex to the EU Certificate no. 51488-60-01-00

Following devices/device categories are included in this certificate:

Class III

Name of the device/ device category:

- Suprathel, Suprathel 250, SupraSDRM, SupraSDRM 1100,

  Basis-UDI-DI 426018402AAA0000001PQ

For the initial placing on the market of class III devices covered by this certificate, an EC EU technical documentation assessment certificate according to Regulation (EU) 2017/745 Annex IX Chapter II is required.

Change to previous certificate: Change of address of the legal manufacturer.