

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: SupraSDRM, SupraSDRM 1100

EU Certificate no.: 51488-61-B1-00

Certificate valid from:

2024-05-21

Certificate valid to:

2028-05-16

Previous certificate no. 51488-61-B0, issued on 2023-05-17



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

DEKRA Certification GmbH, Stuttgart 2024-05-21
Notified Body ID number: 0124

Annex to the EU Certificate no. 51488-61-B1-00

Report Number: 51488-TD2-01 / 51488-CN24-01

Product: SupraSDRM, SupraSDRM 1100

Basis-UDI-DI: 426018402AAA0000001PQ

Risk Classification: Class III

Intended Use:

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

Technical Data:

SupraSDRM 1.500 – 2.100 µm	Size	Item number
	Ø 12 mm	31D012-MDR
	Ø 18 mm	31D018-MDR
	Ø 24 mm	31D024-MDR
	1 x 1 cm	310101-MDR
	2 x 2 cm	310202-MDR
	4 x 4 cm	310404-MDR
	5 x 5 cm	310505-MDR
	9 x 9 cm	310909-MDR
	9 x 12 cm	310912-MDR
	18 x 9 cm	311809-MDR
	18 x 18 cm	311818-MDR

SupraSDRM 1100 800 – 1.400 µm	Size	Item number
	Ø 12 mm	31D012-1100-MDR
	Ø 18 mm	31D018-1100-MDR
	Ø 24 mm	31D024-1100-MDR
	1 x 1 cm	310101-1100-MDR
	2 x 2 cm	310202-1100-MDR
	4 x 4 cm	310404-1100-MDR
	5 x 5 cm	310505-1100-MDR
	9 x 9 cm	310909-1100-MDR
	9 x 12 cm	310912-1100-MDR
	18 x 9 cm	311809-1100-MDR
	18 x 18 cm	311818-1100-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



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BS-MDR-092

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

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.