EU Technical Documentation Assessment Certificate

This is to certify that the company

3M Deutschland GmbH

Carl-Schurz-Str. 1
41453 Neuss
Germany

SRN: DE-MF-000011641

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	31621516 MDR2017P
Certificate ID	1000159768
Effective date	2024-02-28
Expiry date	2029-02-27
Frankfurt am Main,	2024-02-28

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000011641
Certificate ID: 1000159768

Device categories and variants covered by this certificate:

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040410 – Dressings, Animal-Derived Collagen**
Product name:	Promogran™ Collagen Matrix with ORC
Models:	M770285, M772028, M771235, M772123
Risk classification:	III
Basic-UDI-DI:	06082232761010000000043CV
Intended purpose:	Promogran™ is intended to be used for the management of wounds which are clear of necrotic tissue.

Examinations and tests performed:
003626_A211197MED dated 2024-01-23

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	n/a	n/a	n/a