EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH
Health Care Business
Single Registration Number: DE-MF-000011641
Carl-Schurz-Str. 1
41453 Neuss
Germany

hereby declare under our sole responsibility that the following CE marked device

Trade Name	Promogran™ Collagen Matrix with ORC
Intended Purpose	Intended to be used in the management of wounds which are clear of necrotic tissue.
Reference	M770285, M772028, M772123, M771235
Basic UDI-DI	06082232761010000000043CV

is classified per rule 18 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class III device in accordance with Annex IX and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the EU Quality Management Certificate and EU Technical Documentation Assessment Certificate:

EU Quality Management Certificate: 003626 MDR2017Q
EU Technical Documentation Assessment Certificate: 31621516 MDR2017P

Issued by: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany No. 0297

Harald Ceschinski
Sr. Mgr. RA & Quality Compliance
Health Care Business EMEA
3M Deutschland GmbH

Neuss / March 20, 2024
Location/Date