# *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* | Tegaderm™ High Performance Foam Non-Adhesive Dressing |
| Intended Purpose | Tegaderm High Performance Foam Non-Adhesive Dressing is intended for use as a primary or secondary dressing for low- to highly exuding partial and full thickness wounds. The dressing is suitable for use around tube exit sites and with compression therapy. |
| Reference | 90600; 90601; 90602; 90603; 90604 |
| Basic UDI-DI | 06082232761010000000049D9 |

is classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIb devices 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 quality certificate
EU Quality Management Certificate: 003626MDR2017Q
Issued by: DQS Medizinprodukte GmbH, No. 0297
August-Schanz Straße 21, D-60433 Frankfurt am Main

C. Inden

Neuss, June 10, 2024

Claudia Inden
Manager Regulatory Affairs
Medical Surgical Business
3M Deutschland GmbH

Location/Date