# *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 devices

| | |
|---|---|
| Trade Name | 3M™ Actisorb™ Plus 25 Activated Charcoal Dressing with Silver<br>3M™ Actisorb™ Ag+ Pansement au Charbon Actif et Argent |
| Intended Purpose | Management of all chronic wounds including fungating carcinomas, traumatic and surgical wounds where bacterial contamination, infection or odour occurs |
| Reference | MAP065, MAP105, MA105E, MAP190<br>MA105FH, MA190FH |
| Basic UDI-DI | 06082232761010000000045CZ |

are classified per rule 14 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class III 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 EU Quality Management Certificate and EU Technical Documentation Assessment Certificate:

EU Quality Management Certificate: 003626MDR2017Q
EU Technical Documentation Assessment Certificate: 31619999MDR2017P

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

Margaret Bessenbach

Margaret Bessenbach
Director Regulatory Affairs and Quality
Health Care Business EMEA
3M Deutschland GmbH

Neuss, January 09, 2024
Location/Date