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	Nu-Gel™ Hydrogel with Alginate
Intended Purpose	Nu-Gel™ Hydrogel with Alginate is a transparent hydro active amorphous gel that can be used to soften and hydrate eschar by facilitating rehydration of the wound. The hydrogel component creates a moist healing environment that assists in natural autolytic debridement and the alginate component serves to enhance absorption capabilities.
Reference	MNG415, MNG425, MNG515E, MNG415N, MNG425N
Basic UDI-DI	06082327610100000000038D4

is classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIb 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 quality certificate
EU Quality Management Certificate: 003626MDR2017Q
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, August 29, 2023
Location/Date