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	3M™ Inadine™ (PVP-I) Non-Adherent Dressing
Intended Purpose	Inadine™ dressing is indicated for the management of ulcerative wounds, minor burns and minor traumatic skin loss injuries. Inadine™ dressing is designed to protect and minimize adherence to the wound bed and provides an antiseptic effect against bacterial organisms. In heavily infected wounds, systemic antibiotics may be used in conjunction with Inadine dressing.
Reference	P01481, P01491, P01512
Basic UDI-DI	06082232761010000000035CW

is classified per rule 14 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: 003626MDR2017Q
EU Technical Documentation Assessment Certificate: 003626MDR2017P
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, October 6, 2023
Location/Date