

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 TM Inadine TM (PVP-I) Non-Adherent Dressing
Intended	Inadine TM dressing is indicated for the management of
Purpose	ulcerative wounds, minor burns and minor traumatic skin
	loss injuries. Inadine TM 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

Director Regulatory Affairs and Quality

Margaret Bessenbach

Health Care Business EMEA

3M Deutschland GmbH

3M is a trademark of 3M.

Neuss, October 6, 2023 Location/Date