

## **EUROPEAN MEDICAL DEVICE REGULATION**

## **Declaration of Conformity**

As Legal Manufacturer, we

Solventum Germany GmbH Edisonstrasse 6, 59174 Kamen, Germany Single Registration Number: DE-MF-000038373

hereby declare under our sole responsibility that the following CE marked device

Trade Name	Solventum™ 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	0197998276101000000035Q7

is 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 quality certificates

**EU Quality Management Certificate:** 31619899MDR2017Q EU Technical Documentation Assessment Certificate: 31619899MDR2017P

Issued by: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main,

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Claudia Inden Location/Date

Senior Manager Regulatory Affairs

Medical Surgical (MedSurg) Business

Kamen, March 27, 2025