



# EU Technical Documentation Assessment Certificate

This is to certify that the company

## Solventum Germany GmbH

Edisonstrasse 6  
59174 Kamen  
Germany

SRN: DE-MF-000038373

has established and maintains the required Technical Documentation in accordance with

### Annex IX, Chapter II of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of  
Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity  
Assessment Procedures according to Article 52. The Technical Documentation is subject to  
regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2  
listed in the Annex may bear the CE marking with the identification number of the Notified Body  
(0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex  
IX, Chapter I and III is required.

Certificate registration no.	31619899 MDR2017P
Certificate ID	1000232050
Effective date	2025-06-12
Expiry date	2030-03-20
Frankfurt am Main,	2025-06-12



## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745  
of the Council concerning medical devices with the Identification Number 0297.  
The validity of the certification can only be verified by the QR-code.



Annex to EU Technical Documentation Assessment Certificate  
SRN of Manufacturer: DE-MF-000038373  
Certificate ID: 1000232050

Device categories and variants covered by this certificate:

Device category: MDN 1204 - Non-active non-implantable devices for wound and skin care  
M040412 Dressings, with Antiseptics  
Product name: Inadine™ (PVP-I) Non-Adherent Dressing  
Models: P01481, P01481EE, P01491, P01491EE, P01512, P01512EE  
Risk classification: III  
Basic-UDI-DI: 01979982761010000000035Q7  
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

Examinations and tests performed:

31619899\_A215789MED "Inadine™ (PVP-I) Non-Adherent Dressing" dated 2025-02-26  
31619899\_A215789MED "Inadine™ (PVP-I) Non-Adherent Dressing" dated 2025-05-05

Further conditions for or limitations to the validity of the certificate:  
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2025-03-21	1000153314	Report adjustment of Inadine™ (PVP-I) Non-Adherent Dressing