



EU Technical Documentation Assessment Certificate



This is to certify that the company

3M Deutschland GmbH

trading as „Health Care Business“

Carl-Schurz-Str. 1
41453 Neuss
Germany

SRN: DE-MF-000011641

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.

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

Devices of class IIb and III as listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	003626 MDR2017P
Certificate ID	1000135504
Effective date	2023-09-26
Expiry date	2028-08-24
Frankfurt am Main,	2023-09-26



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlf.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)



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 this certificate can only be verified by the QR-code.



Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000011641
Certificate ID: 1000135504

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:	06082232761010000000035CW
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:

003626_A208828MED dated 2023-07-17

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	2023-08-25	1000132115	Correction of Intended purpose