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.zlg.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.

420.92 Version 5.0

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:	0608223276101000000035CW
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

EU Quality Management 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, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III 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.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	003626 MDR2017Q
Certificate ID	1000134651
Effective date	2023-08-25
Expiry date	2027-02-22
Frankfurt am Main,	2023-08-25

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

DQS Medizinprodukte GmbH

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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.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000011641
Certificate ID: 1000134651

Device categories covered by this certificate:

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Risk classification:	Is
Intended purpose:	Non-woven adhesive dressings, with absorbent pad, Cotton gauzes; Prepared Dressings
Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Risk classification:	IIa
Intended purpose:	Polyurethane fixing dressings, non-woven fixing dressings, Polysaccharide hemostatic dressings, Polyurethane adhesive dressings, with absorbent pad
Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Risk classification:	IIb
Intended purpose:	Absorbent Dressings (adhesive, non-adhesive), non-antimicrobial, exudate absorbent, wound adherent, wound non-adherent for wound and skin care Absorbent Dressings
Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **MDT 2006 - Devices manufactured using chemical processing**
Risk classification:	IIa
Intended purpose:	Cryotherapy and thermotherapy devices
Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Risk classification:	IIb
Intended purpose:	Dressings, Hydrogel
Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Risk classification:	IIb
Intended purpose:	Dressings, Activated Charcoal
Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Risk classification:	IIb
Intended purpose:	Dressings, Cellulose Associated or Not Associated

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000011641
Certificate ID: 1000134651

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040412 - Dressings with Antiseptics**
Risk classification:	III
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_A208770MED_01 dated 2021-10-14

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-02-23	170776716	Addition Nexcare Cold Instant Therapy Pack
02	2022-05-12	170780118	New revised Certificate Edition (no changes to the content of the products)
03	2022-08-16	170781007	Change of the Intended purpose
04	2022-11-16	170782077	Addition of the product „3M™ Kerralite Cool™" and "Kerracel Gelling Fiber Dressing
05	2023-07-31	1000130385	Addition Inadine