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.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 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	1000186334
Effective date	2024-07-11
Expiry date	2027-02-22
Frankfurt am Main,	2024-07-11

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 the certification can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000011641
Certificate ID: 1000186334

Device categories and variants 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:	IIa
Intended purpose:	Cryotherapy and thermotherapy devices

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040204 - Absorbent Dressings, Wound-Nonadherent**
Product name:	Tegaderm™ High Performance Foam Adhesive Dressing Tegaderm™ High Performance Foam Non-Adhesive Dressing Tegaderm™ Foam Adhesive Dressing with Soft Cloth Border Tegaderm™ Silicone Foam Dressing Tegaderm™ Silicone Foam Border Dressing
Risk classification:	IIb
Basic-UDI-DI:	06082232761010000000034CU 06082232761010000000049D9 06082232761010000000046D3 06082232761010000000047D5
Intended purpose:	Product is intended for use as foam dressing for up to highly exuding partial and full thickness wounds

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040204 - Absorbent Dressings, Wound-Nonadherent**
Product name:	Tegaderm™ Absorbent Clear Acrylic Dressing
Risk classification:	IIb
Basic-UDI-DI:	06082232761010000000050CS
Intended purpose:	Product is intended to be used for skin injuries to absorb wound fluid. It may also be used to protect undamaged or at-risk skin

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Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040204 - Absorbent Dressings, Wound-Nonadherent**
Product name:	Kerramax Care™ Super-Absorbent Dressing Kerramax Care™ Border Super-Absorbent Dressing
Risk classification:	IIb
Basic-UDI-DI:	06082238401010000000198BA 06082238401010000000199BC
Intended purpose:	Product is a non-invasive device, intended for short term use in the management of moderate to heavily exuding wounds, which have breached the dermis on injured skin and can only heal by secondary intent

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040204 - Absorbent Dressings, Wound-Nonadherent**
Product name:	Adaptic™ Touch Non-Adhering Silicone Dressing Adaptic™ Non-Adhering Dressing
Risk classification:	IIb
Basic-UDI-DI:	06082238401010000000194B2 06082238401010000000193AY
Intended purpose:	Product is intended to be used as a primary wound contact layer and prevents adherence of a secondary dressing to the wound

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040404 - Dressings, Cellulose Associated or Not Associated**
Product name:	Kerracel™ Gelling Fiber Dressing
Risk classification:	IIb
Basic-UDI-DI:	06082238401010000000201A6
Intended purpose:	The product is designed for the management of moderately to heavily exuding partial and full-thickness chronic wounds and acute wounds, and to control minor bleeding in superficial wounds

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040405 – Dressing, Hydrogel**
Product name:	Kerralite Cool™ Moisture Balancing Hydrogel Dressing Kerralite Cool™ Border Moisture Balancing Hydrogel Dressing
Risk classification:	IIb
Basic-UDI-DI:	06082238401010000000203AA
Intended purpose:	The product encourages wound bed preparation and granulation of chronic wounds, while minimizing pain levels. The dressing helps to provide an environment for optimal wound healing by managing wound exudate levels and protecting against wound dehydration and external bacterial contamination. The gel provides both cushioning and absorption. The partially-hydrated nature of the dressing aids the process of autolytic debridement and helps soothe the wound on contact

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Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040405 – Dressing, Hydrogel**
Product name:	Nu-Gel™ Hydrogel with Alginate
Risk classification:	IIb
Basic-UDI-DI:	0608223276101000000038D4
Intended purpose:	Product is a transparent hydro active amorphous gel that can be used to soften and hydrate eschar by facilitating rehydration of the wound. The hydrogel component creates a moist healing environment that assists in natural autolytic debridement and the alginate component serves to enhance absorption capabilities.

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040405 – Dressing, Hydrogel**
Product name:	Solugel™ Wound Care Gel
Risk classification:	IIb
Basic-UDI-DI:	0608223276101000000039D6
Intended purpose:	Product is designed to provide a soothing, moist wound healing environment.

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040409 - Dressings, Activated Charcoal**
Product name:	Odolock™ Activated Charcoal Dressing Actisorb™ Pansement Au Charbon Actif Actisorb™ Silberfrei Aktivkohlewundauflage
Risk classification:	IIb
Basic-UDI-DI:	060822384010100000000197B8
Intended purpose:	The product is intended to be used in the management of wound malodor

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
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

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Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040408- Dressings, Silver**
Product name:	Actisorb Ag Silver containing Dressing Product Family
Risk classification:	III
Basic-UDI-DI:	06082232761010000000041CR (Actisorb Silver 220), 06082232761010000000045CZ (Actisorb Plus 25 and Actisorb Ag+)
Intended purpose:	Management of all chronic wounds including fungating carcinomas, traumatic and surgical wounds where bacterial contamination, infection or odour occurs

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040410 – Dressings, Animal-Derived Collagen**
Product name:	Promogran™ Collagen Matrix with ORC
Risk classification:	III
Basic-UDI-DI:	06082232761010000000043CV
Intended purpose:	Product is intended to be used for the management of wounds which are clear of necrotic tissue

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040410 – Dressings, Animal-Derived Collagen**
Product name:	Promogran Prisma™ Collagen Matrix with ORC and Silver Promogran™ Plus Collagen Matrix with ORC and Silver
Risk classification:	III
Basic-UDI-DI:	06082232761010000000044CX
Intended purpose:	Product is intended to be used for the management of wounds which are clear of necrotic tissue

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care** **M040410 – Dressings, Animal-Derived Collagen**
Product name:	FIBRACOL™ PLUS Collagen Wound Dressing with Alginate
Risk classification:	III
Basic-UDI-DI:	06082232761010000000040CP
Intended purpose:	FIBRACOL™ Plus dressing maintains a physiologically moist microenvironment at the wound surface that is conducive to granulation tissue formation, epithelialization, and enables healing to proceed at a rapid rate

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Examinations and tests performed:
003626_A208770MED_01 dated 2021-10-14
003626_3M_Report_TechnicalFileReviewMedipore_V2 dated 2021-09-21
003626_Report_Technical_File_Review_3M_Tegaderm_Transparent_Film dated 2022-01-27
003626_A208724MED_01 dated 2021-11-11
003626_A208770MED_01 dated 2021-10-14
2022-02-27_A208724MED_003626_420_12e_Report_TechnicalFileReview_3M_Nexcare_ Cold_ Instant dated 2022-04-01
003626 A210378MED MDR2017B Kerracel Gelling Fiber Dressing dated 2022-11-22
003626 A210378MED MDR2017B 3M™ Kerralite Cool™ dated 2023-07-18

Further conditions for or limitations to the validity of the certificate:
In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

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
06	2023-08-25	1000134651	Addition of the product Actisorb Ag Silver containing Dressing Product Family
07	2023-12-21	1000137746	Addition of the product "Promogran™ Collagen Matrix with ORC"
08	2024-02-28	1000159646	Addition of the product FIBRACOL PLUS Collagen Wound Dressing with Alginate
09	2024-03-25	1000169238	Addition of the product Nu-Gel™ Hydrogel with Alginate, Solugel™ Wound Care Gel

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10	2024-04-25	1000171959	Addition of the product Promogran Prisma™ Collagen Matrix with ORC and Silver, Promogran Plus™ Collagen Matrix with ORC and Silver
11	2024-05-08	1000175679	Addition of the Basic-UDI for Tegaderm™ Silicone Foam Dressing Tegaderm and Silicone Foam Border Dressing