EU Quality Management Certificate

This is to certify that the company

Solventum Germany GmbH

Edisonstrasse 6
59174 Kamen
Germany

SRN: DE-MF-000038373

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.	31619899 MDR2017Q
Certificate ID	1000246349
Effective date	2025-06-12
Expiry date	2029-08-13
Frankfurt am Main,	2025-06-12

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000038373
Certificate ID: 1000246349

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, 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 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 Border Dressing Tegaderm™ Silicone Foam Dressing
Risk classification:	IIb
Basic-UDI-DI:	01979982761010000000034Q5 01979982761010000000254QM 01979988401010000000263N5 01979982761010000000266QU (Made in Germany) 01979988401010000000265N9 (Made in US)
Intended purpose:	Product is intended for use as foam dressing for low 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:	01979982761010000000259QX
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:	01979982761010000000255QP 01979982761010000000256QR
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:	01979982761010000000258QV 01979982761010000000257QT
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:	01979982761010000000216QD
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:	01979982761010000000217QF
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:	01979982761010000000248QS
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:	01979982761010000000249QU
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:	01979982761010000000215QB
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 M040408- Dressings, Silver
Product name:	Actisorb Ag Silver containing Dressing Product Family
Risk classification:	III
Basic-UDI-DI:	01979982761010000000041Q2, 01979982761010000000252QH
Intended purpose:	Management of all chronic wounds including fungating carcinomas, traumatic and surgical wounds where bacterial contamination, infection or odour occurs

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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:	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
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:	01979982761010000000043Q6
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:	01979982761010000000044Q8
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:	01979982761010000000040PY
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

Examinations and tests performed:
31619899_A215714MED Solventum™ Tegaderm™ Transparent Film Dressing with Border dated 2025-01-13
31619899_A215677MED Solventum™ Kerracel Gelling Fiber Dressing dated 2025-01-06
31619899_A215677MED Solventum™ Kerralite Cool™ / Border Moisture Balancing Hydrogel Dressings dated 2025-01-13
31619899_A215679MED Solventum™ Actisorb_Odolock_Actisorb Silberfrei dated 2025-01-06
31619899_A216015MED Actisorb Ag Silver dated 2025-01-13
31619899_A215789MED "Inadine™ (PVP-I) Non-Adherent Dressing" dated 2025-02-26
31619899_A216087MED "Medipore+Pad Adhesive Wound Dressing" dated 2025-04-04
31619899_A216087MED "Solventum™ Tegaderm™ High Performance Foam Dressings" dated 2025-04-04
31619899_A216142MED "Promogran™ Collagen Matrix with ORC" dated 2025-04-16
31619899_A216142MED "Promogran Prisma /Promogran Plus Collagen Matrix with ORC and Silver" dated 2025-04-16
31619899_A216132MED FIBRACOL™ PLUS Collagen Wound Dressing with Alginate dated 2025-04-16
31619899_A215789MED "Inadine™ (PVP-I) Non-Adherent Dressing" dated 2025-05-05

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.

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Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2025-02-25	1000142331	Addition “Inadine™ (PVP-I) Non-Adherent Dressing”
02	2025-03-21	1000222210	Addition “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”, “Tegaderm™ Absorbent Clear Acrylic Dressing”, “Kerramax Care™ Super-Absorbent Dressing, Kerramax Care™ Border Super-Absorbent Dressing”, “Adaptic™ Touch Non-Adhering Silicone Dressing, Adaptic™ Non-Adhering Dressing”
03	2025-04-10	1000232051	Addition “Promogran™ Collagen Matrix with ORC”, “Promogran Prisma /Promogran Plus Collagen Matrix with ORC and Silver”, “FIBRACOL™ PLUS Collagen Wound Dressing with Alginate”
04	2025-04-17	1000233482	Report adjustment of Inadine™ (PVP-I) Non-Adherent Dressing