ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 046241 0073 Rev. 02

Manufacturer:

Winner Medical Co., Ltd.
Winner Industrial Park
No. 660 Bulong Road
Longhua District
518109 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000005692

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 046241 0073 Rev. 02

Report No.:	SH25004301
Preceding Certificate No.:	G10 046241 0073 Rev. 01
Valid from:	2025-06-24
Valid until:	2028-07-09
Date of Initial Issuance:	2023-07-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-06-24

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Classification:	Class IIa
Device Group:	M02010202 - COTTON GAUZES, FOLDED, WITH X-RAY DETECTABLE THREAD
Intended Purpose:	-

Classification:	Class IIb
Device Group:	M040402 - ALGINATE DRESSINGS
Intended Purpose:	(1) Alginate dressing (Type I) is a highly conformable and absorbent primary dressing that absorbs wound exudate and maintains a moist environment to promote wound healing. It can also promote hemostasis in minor bleeding wounds. (2) Alginate dressing (Type II) is a highly conformable and absorbent primary dressing that absorbs wound exudate and maintains a moist environment to promote wound healing.

Classification:	Class IIb
Device Group:	M040406 - POLYURETHANE DRESSINGS
Intended Purpose:	(1) Foam dressing without film is a wound dressing that absorbs wound exudate and provides a moist wound healing environment to promote wound healing. (2) Foam dressing without border is a wound dressing that absorbs wound exudate and provides a moist wound healing environment to promote wound healing. (3) Foam dressing with border is a wound dressing that absorbs wound exudate and provides a moist wound healing environment to promote wound healing.

Classification:	Class IIb
Device Group:	M040407 - SILICONE DRESSINGS
Intended Purpose:	(1) Silicone foam dressing with border is a wound dressing that absorbs wound exudate and provides a moist wound healing environment to promote wound healing. It can also prevent pressure ulcer. (2) Silicone foam dressing without border is a highly conformable dressing that absorbs exudates, maintains a moist wound environment to promote wound healing. (3) Silicone foam lite dressing with border is a self-adherent, absorbent dressing that maintains a moist wound environment to promote wound healing. (4) Silicone foam lite dressing without border is a thin and highly conformable foam dressing that absorbs exudate and maintains a moist wound environment to promote wound healing. (5) Transfer silicone foam lite dressing is a thin and highly conformable foam dressing that absorbs exudate and maintains a moist wound environment to promote wound healing.

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No. G10 046241 0073 Rev. 02

Classification:	Class IIb
Device Group:	M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
Intended Purpose:	Super Absorbent Dressing is a highly absorbent wound dressing for the management of moderate to highly exuding wounds. It was designed to absorb wound exudate and provide a moist wound healing environment to promote wound healing.
Classification:	Class IIa
Device Group:	M020299 - NON-WOVEN GAUZES - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	M02020102 - NON-WOVEN FOLDED GAUZES, WITH X-RAY DETECTABLE THREAD
Intended Purpose:	-
Classification:	Class IIb
Device Group:	M040407 - SILICONE DRESSINGS
Intended Purpose:	Silicone Wound Contact Layer- Type I&II: One-side adhesive can be used alone or in combination for exuding wounds, non-exuding wounds, fragile skin areas, or Negative Pressure Wound Therapy (NPWT) systems, thereby non-adherent to the wound and reducing secondary trauma. When the product is used alone, it acts as a mechanical barrier as a protective layer. When the product is used in combination, it can be used as an isolation layer between the wound and secondary absorbent dressings. Silicone Wound Contact Layer- Type III: Two-side adhesive can be used as an isolation layer between the wound and secondary absorbent dressings, for exuding wounds, non-exuding wounds, fragile skin areas, or Negative Pressure Wound Therapy (NPWT) systems, thereby non-adherent to the wound and reducing secondary trauma.
Classification:	Class IIb
Device Group:	M040409 - ACTIVATED CHARCOAL DRESSINGS
Intended Purpose:	Activated Charcoal Super Absorbent Dressing is an absorbent dressing for exudate management and reduction of malodour, it can be used on acute and hard-to-heal wounds producing all volumes and types of exudate, including high viscosity. Can be used on malodorous, infected and susceptible wounds.

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No. G10 046241 0073 Rev. 02

Classification:	Class IIb
Device Group:	M040407 - SILICONE DRESSINGS
Intended Purpose:	Silicone Super Absorbent Dressing without Border (Type I and Type II) is suitable for treatment of injured skin, acute and chronic wounds, with moderate to heavily exudate. Silicone Super Absorbent Dressing with Border (Type I and Type II) is suitable for the treatment of injured skin, acute and chronic wounds, with moderate to heavily exudate.
Classification:	Class IIb
Device Group:	M040403 - HYDROCOLLOID DRESSINGS
Intended Purpose:	Hydrocolloid Dressing Standard/Thin is intended for management of non- to low-exuding wounds that the injuries to skin have breached epidermis or dermis, such as donor sites, postoperative wounds and skin abrasions. Hydrocolloid Dressing with Tapered Edges is intended for management of non- to moderate-exuding wounds that the injuries to skin have breached epidermis or dermis, such as pressure ulcers, leg ulcers, donor sites, postoperative wounds and skin abrasions.
Classification:	Class IIb
Device Group:	M040404 - CELLULOSE AND/OR MODIFIED CELLULOSE DRESSINGS, NON-COMBINED OR COMBINED WITH OTHER SUBSTANCES
Intended Purpose:	CMC Gelling Fiber Dressing is intended for the management of moderately to heavily exuding wounds that the injuries to skin have breached epidermis or dermis, such as leg ulcers, pressure ulcers (Stage II-IV), diabetic ulcers, surgical wounds (e.g., post-operative, wounds left to heal by secondary intent and donor sites), partial thickness burns, traumatic wounds (e.g., abrasions and lacerations).
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2023-07-10	SH22043MDR	Initial issuance
01	2024-06-11	SH2304301	Supplemented: Device(s)/group of device(s) added
02	2025-06-24	SH25004301	Supplemented: Change to the approved type(s)/device(s)

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