

**EU Declaration of Conformity****Silicone Foam Dressing**

This Declaration of Conformity is issued under the sole responsibility of Winner Medical Co., Ltd.

We hereby declare that the mentioned product/ attached list of products with CE marking comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745. And the CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

<b>Legal Manufacturer:</b>	Winner Medical Co., Ltd. Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
<b>SRN:</b>	CN-MF-000005692
<b>Authorized Representative:</b>	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
<b>SRN:</b>	DE-AR-000000001
<b>Product Name:</b>	Refer to Appendix A
<b>EMDN Code and Term Description:</b>	Refer to Appendix A
<b>Basic UDI-DI:</b>	Refer to Appendix A
<b>Intended Purpose:</b>	Refer to Appendix A
<b>Risk Classification:</b>	Class IIb as per Rule 4 in Annex VIII of EU Medical Device Regulation (EU) 2017/745
<b>Conformity Assessment Route:</b>	Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIb Devices)
<b>Applicable Standards:</b>	EN ISO 13485: 2016 EN ISO 14971: 2019 EN ISO 20417: 2021 EN ISO 15223-1: 2021 EN ISO 10993-1: 2020 EN ISO 11135: 2014/A1: 2019 ISO 10993-7: 2008/Amd 1: 2019

	EN ISO 11737-1: 2018 EN ISO 11737-2:2020 EN 13726: 2023
References to any CS:	Not Applicable
Identification of Notified Body:	TÜV SÜD Product Service GmbH 0123 Zertifizierstelle, Ridlerstraße 65, 80339 München, GERMANY
Identification of the Certificate(s):	EU Quality Management System Certificate (MDR) No. G10 046241 0073 Rev.02, issued by TÜV SÜD Valid from: 2025-06-24 Valid until: 2028-07-09
Identification of the person authorized to sign on behalf of Legal Manufacturer:	<b>Name:</b> Xiaomeng Yang  <b>Signature:</b> <u>Xiaomeng Yang</u>  Management Representative Place of Issue: Shenzhen, China Date: 2025-06-24

## Appendix A: List of Product Range Covered under this Declaration of Conformity

General Device Group	Product	EMDN Code	Risk Classification	Basic UDI-DI
Silicone Foam Dressing	Silicone Foam Dressing With Border (Type I)	M04040701 SILICONE DRESSINGS, NON-COMBINED	Class IIb Rule 4	694232708961GJ
	Silicone Foam Dressing With Border (Type II)			694232707997GY
	Silicone Foam Dressing Without Border			694232708964GQ
	Silicone Foam Lite Dressing With Border (Type I)			694109403528EV
	Silicone Foam Lite Dressing With Border (Type II)			694232708963GN
	Silicone Foam Lite Dressing With Border (Type III)			694232708962GL
	Silicone Foam Lite Dressing Without Border (Type I)			694232708965GS
	Silicone Foam Lite Dressing Without Border (Type II)			694232708000EH
	Silicone Foam Lite Dressing Without Border (Type III)			694232707998H2
	Transfer Silicone Foam Lite Dressing (Type I)			694232707996GW
	Transfer Silicone Foam Lite Dressing (Type II)			694232707995GU

### Intended purpose & Indications

- Silicone foam dressing with border (Type I)

#### Intended purpose

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.

#### Indications

Silicone foam dressing with border (Type I) is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g., skin tears) and surgical wounds. It can also be used on dry/necrotic wounds in combination with gels. Silicone foam dressing with border reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage (e.g., pressure ulcers).

- Silicone foam dressing with border (Type II)

#### Intended purpose

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.

#### Indications

Silicone foam dressing with border (Type II) is designed for wound management by secondary intention on shallow, granulating wounds, chronic and acute exudative wounds, full and partial thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, first- and second-degree burns, donor sites, skin tears, and fungating ulcers. It can also be used on dry/necrotic wounds in combination with gels and may also be used as part of a prophylactic therapy to help prevent skin damage (e.g., pressure ulcers).

- Silicone foam dressing without border

#### Intended purpose

Silicone foam dressing without border is a highly conformable dressing that absorbs exudates, maintains a moist wound environment to promote wound healing.

#### Indications

Silicone foam dressing without border is designed for a wide range of exuding wounds such as leg and foot ulcers, pressure ulcers and traumatic wounds, e.g., skin tears and secondary healing wounds.

- Silicone foam lite dressing with border (Type I)

#### Intended purpose

Silicone foam lite dressing with border is a self-adherent, absorbent dressing that maintains a moist wound environment to promote wound healing.

#### Indications

Silicone foam lite dressing with border (Type I) is designed for the management of a wide range of non/low exuding wounds, such as leg and foot ulcers, pressure ulcers, surgical wounds and traumatic wounds, e.g., abrasions, blisters and skin tears.

- Silicone foam lite dressing with border (Type II)

#### Intended purpose

Silicone foam lite dressing with border is a self-adherent, absorbent dressing that maintains a moist wound environment to promote wound healing.

#### Indications

Used by or under the supervision of the healthcare professional:

Silicone foam lite dressing with border (Type II) is indicated for wound management on shallow, granulating wounds, acute and chronic exudative wounds, full and partial thickness wounds (such as pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, first and second degree burns, donor sites, skin tears). It can also be used for the prevention of medical device related pressure injuries on intact skin, as part of a pressure injury prevention protocol.

Available for household consumer:

Silicone foam lite dressing with border (Type II) is indicated for wound management of superficial exudative wounds (such as minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds, minor burns, etc.), or for the prevention pressure injuries to intact skin.

- Silicone foam lite dressing with border (Type III)

#### Intended purpose

Silicone foam lite dressing with border is a self-adherent, absorbent dressing that maintains a moist wound environment to promote wound healing.

#### Indications

Used by or under the supervision of the healthcare professional:

Silicone foam lite dressing with border (Type III) is indicated for wound management on shallow, granulating wounds, acute and chronic exudative wounds, full and partial thickness wounds (such as pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, first and second degree burns, donor sites, skin tears). It can also be used for the prevention of medical device related pressure injuries on intact skin, as part of a pressure injury prevention protocol.

Available for household consumer:

Silicone foam lite dressing with border (Type III) is indicated for wound management of superficial exudative wounds (such as minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds, minor burns, etc.), or for the prevention pressure injuries to intact skin.

- Silicone foam lite dressing without border (Type I)

Intended purpose

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.

Indications

Silicone foam lite dressing without border (Type I) is designed for the management of a wide range of non to low exuding wounds such as leg and foot ulcers, pressure ulcers, partial thickness burns.

- Silicone foam lite dressing without border (Type II)

Intended purpose

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.

Indications

Silicone foam lite dressing without border (Type II) is designed to manage a wide range of non- to low-exuding wounds, such as leg ulcers, foot ulcers, pressure ulcers, and partial-thickness burns. It can also be used as protection of compromised and/or fragile skin.

- Silicone foam lite dressing without border (Type III)

Intended purpose

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.

Indications

Silicone foam lite dressing without border (Type III) is designed to manage a wide range of non- to low-exuding wounds, such as leg ulcers, foot ulcers, pressure ulcers, and partial-thickness burns. It can also be used as protection of compromised and/or fragile skin.

- Transfer silicone foam lite dressing (Type I)

Intended purpose

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.

Indications

Transfer silicone foam lite dressing is intended for a wide range of exuding wounds, and can also be used as protection of compromised and/or fragile skin.

- Transfer silicone foam lite dressing (Type II)

Intended purpose

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.

Indications

Transfer silicone foam lite dressing is intended for a wide range of exuding wounds, and can also be used as protection of compromised and/or fragile skin.





Revision History

Rev No.	Date	Comment	Author
A/0	2023-07-10	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Ziling Shangguan
A/1	2024-06-11	Update for the new certificate version	Ziling Shangguan
A/2	2025-06-24	Product changes, adding new models	Ziling Shangguan

# Annex to EU Declaration of Conformity (No.: WN-CE (MDR) 52-13 A/2)

The following Product names and Article codes are covered by the EU Declaration of Conformity (Doc No.: WN-CE (MDR) 52-13 A/2, certificate No. G10 046241 0073 Rev. 02).

Winner Product	EMDN code	Basic UDI-DI	B.Braun Code	Product description
Silicone Foam Dressing With border (TYPE I)	M04040701	694232708961GJ	WIN5397510	Askina® DresSil Active Border 7,5 x 7,5cm
			WIN5391010	Askina® DresSil Active Border 10 x 10cm
			WIN5391110	Askina® DresSil Active Border 12,5 x 12,5cm
			WIN5391510	Askina® DresSil Active Border 15 x 15cm, 10 Pack
			WIN5391503	Askina® DresSil Active Border 15 x 15cm, 3 Pack
			WIN5395210	Askina® DresSil Active Border 15 x 20cm
			WIN5592205	Askina® DresSil Active Border Heel 23,5 x 24,5cm
			WIN5491605	Askina® DresSil Active Border Sacrum 18 x 20cm
			WIN5492105	Askina® DresSil Active Border Sacrum 23 x 23cm
Silicone foam dressing without border		69423708964GQ	WIN5291003	Askina® DresSil 10 x 10cm 3 Pack
			WIN5291010	Askina® DresSil 10 x 10cm, 10 Pack
			WIN5291505	Askina® DresSil 15 x 15cm, 5 Pack
			WIN5292005	Askina® DresSil 20 x 20cm, 5 Pack

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.

