

EU Declaration of Conformity

Non-woven Wound Dressing (Class Is)

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.

Legal Manufacturer:	Winner Medical Co., Ltd. Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000005692
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
SRN:	DE-AR-000000001
Product Name:	Refer to Appendix A
EMDN Code and Term Description:	Refer to Appendix A
Basic UDI-DI:	Refer to Appendix A
Intended Purpose:	Refer to Appendix A
Risk Classification:	Class I Sterile as per Rule 4 in Annex VIII of EU Medical Device Regulation (EU) 2017/745
Conformity Assessment Route:	Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class I Devices in sterile condition)
Applicable Standards:	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

	EN ISO 11607-1: 2020 EN ISO 11607-2: 2020 EN ISO 11737-1: 2018 EN ISO 11737-2: 2020 EN 13726-1: 2002 EN 13726-2: 2002 EN 1644-1: 1997
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. G11 046241 0074 Rev.02, issued by TÜV SÜD Valid from: 2024-10-18 Valid until: 2028-07-09
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Xiaomeng Yang Signature: <u>Xiaomeng Yang</u> Management Representative Place of Issue: Shenzhen, China Date: 2024-10-18

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

General Device Group	Product	EMDN Code	Risk Classification	Basic UDI-DI
Non-woven Wound Dressing	Non-woven Wound Dressing with Pad	M04010101 NON-WOVEN ADHESIVE DRESSINGS, WITH ABSORBENT PAD	Class I Sterile Rule 4	694109409841GE
	Waterproof Non-woven Wound Dressing with Pad			694109409842GG
	Non-woven Wound Dressing for Fixation	M04010201 NON-WOVEN FIXING DRESSINGS		694109409844GL
	Non-woven Wound Dressing Roll			694109409845GN

Intended purpose:

- Non-woven wound dressing with pad is wound treatment device, normally used for the management of postoperative wounds and superficial wounds. It is primarily intended to be used as mechanical barrier, for compression or for absorption of exudates. It is non-invasive and single use device.
- Waterproof non-woven wound dressing with pad is wound treatment device, normally used for the management of post-operative wounds and superficial wounds. It is primarily intended to be used as mechanical barrier, for compression or for absorption of exudates. It is non-invasive and single use device.
- Non-woven wound dressing for fixation is normally designed to meet the needs of catheter fixation and to keep the catheter site dry. Widely used in hospital and clinical settings. It is non-invasive and single use device.
- Non-woven wound dressing roll is normally used for fixing catheters, needles or wound dressings. It is non-invasive and single use device.



Revision History

Rev No.	Date	Comment	Author
A/0	2024-06-11	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Ziling Shangguan
A/1	2024-10-18	Update the certificate version	Ziling Shangguan

Annex to EU Declaration of Conformity**(Doc No.: WN-CE(MDR)84-10 A/1)**

The following Product names and Article codes are covered by the EU Declaration of Conformity (Doc No.: WN-CE(MDR)84-10 A/1, CE certificate No. G11 046241 0074 Rev. 02).

Winner Product	GMDN Code	EMDN Code	Ref Code	Product description
Non-woven wound dressing	16866	M04010101	901211	Cosmopor Kids 7.5 x 5 cm P5 LG1
			901212	Cosmopor Kids 10 x 6 cm P5 LG1
			901213	Cosmopor Kids 7.5 x 5 cm P5 LG2
			901214	Cosmopor Kids 10 x 6 cm P5 LG2
			901215	Cosmopor Kids 7.5 x 5 cm P5 LG3
			901216	Cosmopor Kids 10 x 6 cm P5 LG3
			901217	Cosmopor Kids MIX Sachet P2 LG1
			901218	Cosmopor Kids MIX Sachet P2 LG2
			901219	Cosmopor Kids MIX Sachet P2 LG3

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.

