

EU Declaration of Conformity

Hydrocolloid 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.

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 IIb 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 IIb Devices)
Applicable Standards:	EN ISO 13485: 2016/A11:2021 EN ISO 14971: 2019/A11:2021 EN ISO 20417: 2021 EN ISO 15223-1: 2021 EN ISO 10993-1: 2020 EN ISO 11137-1:2015/A2:2019

	EN ISO 11737-1: 2018/A1:2021 EN ISO 11737-2:2020 EN ISO 11607-1:2020/A1:2023 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:	Name: Xiaomeng Yang Signature: <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	Classification	EMDN Code	Basic UDI-DI
Hydrocolloid Dressing	Hydrocolloid Dressing Standard	Class IIb Rule 4	M04040301	694109403536EU
	Hydrocolloid Dressing Thin			
	Hydrocolloid Dressing with Tapered Edges			

Intended purpose:

- Hydrocolloid Dressing Standard/Hydrocolloid Dressing Thin

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. This dressing is for short-term use (single use time≤7days and accumulated use time≤28 days). This is a professional use only and single use device.

- Hydrocolloid Dressing with Tapered Edges

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. This dressing is for short-term use (single use time≤7days and accumulated use time≤28 days). This is a professional use only 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	Jinling Luo
A/1	2025-06-24	Standards &CE certificate No. updates	Jinling Luo

Annex to EU Declaration of Conformity

(Doc No.: WN-CE(MDR)62-10 A/1)

The following Product names and Article codes are covered by the EU Declaration of Conformity (Doc No.: WN-CE(MDR)62-10 A/1, CE certificate No. G10 046241 0073 Rev.02).

Winner Product	GMDN Code	EMDN Code	Ref Code	Product description
Hydrocolloid Dressing	43186	M04040301	5361100	Hydrocoll Classic, 5x5 cm, P10
			5361110	Hydrocoll Classic, 7.5x7.5 cm, P10
			5361120	Hydrocoll Classic, 10x10 cm, P3
			5361130	Hydrocoll Classic, 10x10 cm, P10
			5361140	Hydrocoll Classic (DE), 10x10 cm, P10
			5361150	Hydrocoll Classic, 15x15 cm, P3
			5361160	Hydrocoll Classic, 15x15 cm, P5
			5361170	Hydrocoll Classic, 20x20 cm, P5
			5361180	Hydrocoll Classic (Thin), 7.5x7.5 cm, P10
			5361190	Hydrocoll Classic (Thin), 10x10 cm, P3
			5361200	Hydrocoll Classic (Thin), 10x10 cm, P10
			5361210	Hydrocoll Classic (Thin), 15x15 cm, P3
			5361220	Hydrocoll Classic (Thin), 15x15 cm, P5
			5361230	Hydrocoll Classic (Sacral), 12x18 cm, P3
			5361240	Hydrocoll Classic (Sacral), 12x18 cm, P5
			5361250	Hydrocoll Classic (Concave), 8x12 cm, P10

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.

