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 EN ISO 14971: 2019 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 EN ISO 11737-2:2020 EN ISO 11607-1:2020 EN 13726-1: 2002 EN 13726-3:2003
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.01, issued by TÜV SÜD Valid from: 2024-06-11 Valid until: 2028-07-09
Identification of the person authorized to sign on behalf of Legal Manufacturer:	**Name:** Xiaomeng Yang **Signature:** Xiaomeng Yang Management Representative Place of Issue: Shenzhen, China Date: 2024-06-11

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