

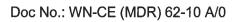
EU Declaration of Conformity

Hydrocolloid Dressing

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

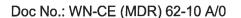
We hereby declare that the mentioned product/ attached list of products with CE marking comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745. And the CE marking is subject to the general principles set out in Article 30 of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

	Winner Medical Co., Ltd.		
Legal Manufacturer:	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-00000001		
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	
	TÜV SÜD Product Service GmbH	
Identification of Notified Body:	0123	
	Zertifizierstelle, Ridlerstraße 65,	
	80339 München, GERMANY	
	EU Quality Management System Certificate (MDR) No.	
Identification of the Certificate(s):	G10 046241 0073 Rev.01, issued by TÜV SÜD Valid from: 2024-06-11	
	Valid Irom: 2024-06-11 Valid until: 2028-07-09	
	Name:	
	Xiaomeng Yang	
Identification of the person authorized to sign on behalf of	Signature: Xianmeng Yang	
Legal Manufacturer:	Management Representative	
	Place of Issue: Shenzhen, China	
	Date: 2024-06-11	



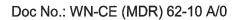


Appendix A: List of Product Range Covered under this Declaration of Conformity

General Device Group	Product	Classification	EMDN Code	Basic UDI-DI
Hydrocolloid Dressing	Hydrocolloid Dressing Standard			
	Hydrocolloid Dressing Thin Class b Rule 4		M04040301	694109403536EU
	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.





Rev No.	Date	Comment	Author
A/0	A/0 2024-06-11	Initial Release of Technical Documentation under	Jinling Luo
A/0 2024-06-11	the Medical Device Regulation (EU) 2017/745	Jillillig Luo	