

## 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.

<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 11137-1:2015/A2:2019

	<p>EN ISO 11737-1: 2018</p> <p>EN ISO 11737-2:2020</p> <p>EN ISO 11607-1:2020</p> <p>EN 13726-1: 2002</p> <p>EN 13726-3:2003</p>
<b>References to any CS:</b>	Not Applicable
<b>Identification of Notified Body:</b>	<p>TÜV SÜD Product Service GmbH 0123</p> <p>Zertifizierstelle, Ridlerstraße 65, 80339 München, GERMANY</p>
<b>Identification of the Certificate(s):</b>	<p>EU Quality Management System Certificate (MDR) No. G10 046241 0073 Rev.01, issued by TÜV SÜD</p> <p>Valid from: 2024-06-11</p> <p>Valid until: 2028-07-09</p>
<b>Identification of the person authorized to sign on behalf of Legal Manufacturer:</b>	<p><b>Name:</b> Xiaomeng Yang</p> <p><b>Signature:</b> <u>Xiaomeng Yang</u></p> <p>Management Representative Place of Issue: Shenzhen, China Date: 2024-06-11</p>

**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 ≤ 7 days 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 ≤ 7 days and accumulated use time ≤ 28 days). This is a professional use only and single use device.

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