EU Declaration of Conformity

1. Products

No.	General Device Group	Product	Classification Rule	Classification	Basic UDI-DI
1	Skin Protective Barrier	Skin Protective Barrier Wipe	Rule 4	Class I Non-sterile	694109405100DZ
2		Skin Protective Barrier Spray			694109403799FW

EMDN Code:
M9002 PROTECTIVE DEVICES, LUBRICANTS AND SOOTHING DEVICES (SPRAYS, GELS, FLUIDS AND CREAMS)

Intended Purpose:
Skin Protective Barrier intended to act as a protective interface between minor wounds or intact skin and body´s wastes, fluids, adhesive dressings, drainage tubes, catheters, and ostomy products to protect the wound from bacteria and dust, provide protection from adhesive trauma, prevent maceration of periwound skin, promote atraumatic dressing removal and help protect areas at risk of friction damage.

2. Manufacturer

Name: Winner Medical Co., Ltd.
Address: Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, CHINA
SRN Number：CN-MF-000005692

3. Authorised Representative

Name: MedPath GmbH
Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN Number：DE-AR-000000087

4. Statement

We hereby declare that the above mentioned products with CE marking meet the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council .The CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.The EU declaration of conformity is issued under the

sole responsibility of the manufacturer.

5. Applicable Standard List

EN ISO 13485: 2016 (ISO 13485: 2016)
EN ISO 14971: 2019 (ISO 14971: 2019)
EN ISO 20417: 2021
EN ISO 15223-1: 2021 (ISO 15223-1: 2021)
EN ISO 10993-1:2020 (ISO 10993-1: 2018)

6. Conformity Assessment Procedure

EU declaration of conformity (Article 19) + technical documentation (Annexes II and III) of Regulation (EU) 2017/745 concerning medical device for Class I (Non-sterile) medical device.

For and on behalf of Winner Medical Co., Ltd.

Xiaomeng, Yang

Xiaomeng, Yang
Management Representative
Shenzhen, China.
Issued Date (YYYY-MM-DD): 2023.08.04

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Annex to EC Declaration of Conformity (Doc No.: WN-CE77-11 A0)

The following Product names and Article codes are covered by the EU Declaration of Conformity - (Doc No.: WN-CE77-11 A0).

Winner Product	EMDN Code	Basic UDI-DI	Product description	Ref Code
Skin protective barrier spray	M9002	694109403799FW	DermaPlast protect spray plaster 30ml LG1	5002010
			DermaPlast protect spray plaster 30ml LG2	5002020
			Tiritas protect spray plaster 30ml LG3	5002030
			Cosmos cover spray plaster 30ml LG4	5002040

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.