

EC Declaration of Conformity

1. Products

Device Group	Products	UMDN Code	Classification rules	Classification
Wound Dressing	Non-woven wound dressing	10276	Rule 4	Class Is
	Transparent wound dressing	10276	Rule 4	Class Is
	Non-adhesive pad	10276	Rule 4	Class Is

2. Manufacturer

Name: Winner Medical Co., Ltd.

Address: Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, CHINA

3. EC- Representative

Name: Shanghai International Holding Corp, GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, Germany

4. Notified Body

Name: TÜV SÜD Product Service GmbH

Identification No.: 0123

Address: Zertifizierstelle, Ridlerstraße 65, 80339 München, GERMANY

5. Statement

We hereby declare that above mentioned products with CE marking meet the provisions of Medical Device Directive (Council directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by directive 2007/47/EC).

6. Applicable Standards

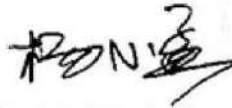
EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2021, EN ISO10993-1 2020, EN ISO 11135:2014/A1:2019, EN ISO 11737-1 2018, EN 1644.1: 1997

7. Conformity Assessment Procedures

EC declaration of conformity (Annex VII) + Production quality assurance (Annex V) of Council directive 93/42/EEC concerning medical devices for Class I (Sterile) medical devices, No. G2S 046241 0064 Rev.04.

2022-07-01

Date (YYYY-MM-DD)



Signature (Yang Xiaomeng, Management Representative)

Annex to EC Declaration of Conformity (Doc.NO: WN-CE11-13 A4)

The following Product names and Article codes are covered by the EC-Declaration of Conformity (Doc.NO: WN-CE11-13 A4 certificate No. G2S 046241 0064 Rev.04).

Device Group	Products	UMDN Code	Classification	B.Braun Code	Product Description
Wound Dressing	Non-woven Wound Dressing	10276	Class Is Rule 4	WIN9086480	Askina® Soft 7.5 X 5 cm
				WIN9086501	Askina® Soft 9 X 5 cm
				WIN9086510	Askina® Soft 9 X 10 cm
				WIN9086528	Askina® Soft 9 X 15 cm
				WIN9086536	Askina® Soft 9 X 20 cm
				WIN9086919	Askina® Soft I.V. 8 x 6 CM
	Non-Adhesive Pad			WIN9024018	Askina® Pad 5 X 5 CM
				WIN9024034	Askina® Pad 10 X 10 CM
				WIN9024042	Askina® Pad 10 X 20 CM
				WIN9024010	Askina® Pad S 10 X 10 CM
				WIN9024050	Askina® Pad S 5 X 5 CM
	Transparent Wound Dressing			WIN9086803	Askina® Soft Clear 7.5 x 5 CM
				WIN9086821	Askina® Soft Clear 9 x 10 CM
				WIN9086830	Askina® Soft Clear 9 x 15 CM
				WIN9086848	Askina® Soft Clear 10 x 25 CM
				WIN9086893	Askina® Soft Clear I.V. 8 x 6 CM
				WINF72032	Askina® Derm Lite 6 x 7 CM
				WINF72033	Askina® Derm Lite 6 x 7 CM
				WINF72034	Askina® Derm Lite 10 x 12 CM
				WINF72035	Askina® Derm Lite 10 x 12 CM
WINF72036	Askina® Derm Lite 10 x 12 CM				
WINF72038	Askina® Derm Lite 15 x 20 CM				

Date: 2023.09.01

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.

