



EC Declaration of Conformity

1. Products

Products	Specifications	GMDN Code	Classification Rules	Classification
Activated charcoal super absorbent dressing	7.5 cm x 7.5 cm 10 cm x 10 cm 10 cm x 15 cm 10 cm x 20 cm 20 cm x 20 cm 20 cm x 25cm 20 cm x 30 cm 30 cm x 30 cm 30 cm x 40 cm 40 cm x 40 cm 50 cm x 50 cm	44897	Rule 4	Class IIb

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 Harmonized Standards

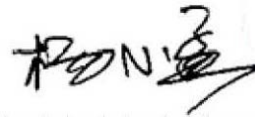
EN ISO 13485:2016, ISO 2859-1:1999, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, ISO 15223-2:2010, EN ISO 14155:2011, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-3:2005, EN ISO 10993-1 2009/ AC:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 10993-12:2012, EN ISO 10993-7:2009, ISO 11135:2014, EN ISO 11137-1:2015, EN ISO 11137-2:2015, ISO 11138-1:2017, ISO 11138-2:2009, ISO 11138-3:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1 2006/ AC:2009, EN ISO 11737-2:2009, ISO 9073-1:1989, EN 13726-1 2002/AC:2003, EN 13726-2:2002, ISO 13726: 2008, ISO 811:2018

7. Conformity Assessment Procedures

Full quality assurance (Annex II) of Council directive 93/42/EEC concerning medical devices for Class IIb medical devices.

2020-06-15

Date (YYYY-MM-DD)



Signature (Yang Xiaomeng, QA Dept.)



Annex to EC Declaration of Conformity (Doc No.: WN-CE21-13 A/1)

The following Product names and Article codes are covered by the EC-Declaration of Conformity (Doc No.: WN-CE21-13 A/1, certificate No. G1 046241 0065 Rev.04.).

Products	GMDN Code	Rules	Classification	B.Braun Code	Brand	Trade Name
Activated charcoal super absorbent dressing	44897	Rule4	Class IIb	WIN9025006	Askina	Askina® Carbosorb
				WIN9025014	Askina	Askina® Carbosorb
				WIN9025015	Askina	Askina® Carbosorb

Signature:

Zhiqin Liang

Date: 2022.8.18

Name and Position: Regulatory Affairs

Company Stamp/Seal

Winner Medical Co., Ltd.

