

EC Declaration of Conformity

1. Products

Products	Specifications	GMDN Code	Classification Rules	Classification
Silicone Contact Layer	5.0 cm x 7.5 cm 7.5 cm x 10.0 cm 10.0 cm x 10.0 cm 10.0 cm x 20.0 cm 17.0 cm x 25.0 cm 24.0 cm x 27.5 cm 20.0 cm x 30.0 cm	46855	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). We take full responsibility for all content in this declaration.

6. Applicable Harmonized Standards

EN ISO 13485:2016 (ISO 13485:2016)
EN ISO 14971:2019 (ISO 14971:2019)
EN ISO 20417:2021 (ISO 20417:2021)
EN ISO 15223-1: 2021 (ISO 15223-1: 2021)
ISO 15223-2:2010
EN ISO 10993-1:2020 (ISO 10993-1:2018)
EN ISO 10993-5:2009 (ISO 10993-5:2009)
EN ISO 10993-6:2016 (ISO 10993-6:2016)
EN ISO 10993-7: 2008/Ac:2009
EN ISO 10993-10:2013 (ISO 10993-10:2010)
EN ISO 10993-11:2018 (ISO 10993-11:2017)
EN ISO 10993-12: 2012 (ISO 10993-12: 2012)
EN ISO 11135:2014/A1:2019 (ISO 11135:2014/Amd 1:2018)
EN ISO 11607-1:2020 (ISO 11607-1:2019)
EN ISO 11607-2:2020 (ISO 11607-2:2019)
EN ISO 11737-1:2018 (ISO 11737-1:2018)
EN ISO 11737-2:2020 (ISO 11737-2:2019)
ISO 29862: 2018
ISO 9073-1-1989
ISO 9073-2: 1996
ISO 9073-3-1989
EN 14079:2003

7. Conformity Assessment Procedures

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

2022-06-21

Date (YYYY-MM-DD)

Signature (Yang Xiaomeng, Management Representative)



Annex to EC Declaration of Conformity (Doc No.: WN-CE20-12 A/3)

The following Product names and Article codes are covered by the EC-Declaration of Conformity (Doc No.: WN-CE20-12 A/3, certificate No. G1 046241 0065 Rev.04).

Winner Product	GMDN Code	EMDN Code	Ref Code	Product description
Silicone Contact Layer	46855	M040407	WIN5195710	Askina® SilNet Plus 5 x 7.5 cm
			WIN5197510	Askina® SilNet Plus 10 x 7.5 cm
			WIN5191010	Askina® SilNet Plus 10 x 10 cm
			WIN5181210	Askina® SilNet Plus 10 x 20 cm
			WIN5192305	Askina® SilNet Plus 20 x 30 cm

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.

