

EU Declaration of Conformity

1. Products

No.	General Device Group	Product	Rule	Risk Class	Basic UDI-DI
1	(Non-sterile) Bandage and Tape product	PBT Elastic Bandage	Rule 1	Class I non-sterile	694109403883FL
2		PE Tape			694109403884FN
3		Paper Tape			694109403887FU
4		Silk Tape			694109403888FW
5		Finger bandage			694109403889FY
6		spandex crepe bandage			694109403890FH
7		Cotton Elastic Bandage			694109403891FK
8		Zinc Oxide Adhesive Plaster			694109403892FM
9		Cotton Cohesive Flexible Bandage			694109403893FP
10		Nonwoven Cohesive Flexible Bandage			694109403894FR
11		Kinesiology Tape			694109403895FT
12		Foam bandage			694109403896FV
13		tubular bandage			694109403897FX
14		Non-woven adhesive bandage			694109403898FZ
15		Cotton Elastic Adhesive Bandage			694109403899G3
16		P.O.P Bandage			694109403900ET

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: Shanghai International Holding Corp, GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, Germany

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.

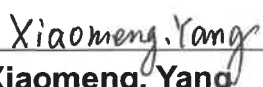
5. Applicable standards

EN ISO 13485:2016 (ISO 13485:2016)
EN ISO 14971:2019 (ISO 14971:2019)
EN 1041:2008+A1:2013
EN ISO 15223-1:2016 (ISO 15223-1:2016)
ISO 15223-2:2016
EN ISO 10993-1:2020 (ISO 10993-1:2018)
EN ISO 10993-5:2009 (ISO 10993-5:2009)
EN ISO 10993-10:2013 (ISO 10993-10:2010)
EN ISO 10993-11:2018 (ISO 10993-11:2017)
EN ISO 11737-1:2018 (ISO 11737-1:2018)
EN ISO 11737-2:2020 (ISO 11737-2:2019)
PSTC-101
PSTC-8
PSTC-107
PSTC-6
BP 1993

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
Management Representative
Shenzhen, China.
Issued Date (YY-MM-DD):2022.02.14

Annex to EC Declaration of Conformity (Doc No.: WN-CE27-13 A1)

The following Product names and Article codes are covered by the EU Declaration of Conformity -
(Doc No.: WN-CE27-13 A1).

Winner Product	EMDN Code	Basic UDI-DI	Product description	Ref Code
(Non-sterile) Bandage and Tape product	M0303	694109403894FR	Peha-haft Easy 6cm x 4m White P1	3000840
			Peha-haft Easy 8cmx4m White P1	3000850
			Peha-haft Easy 6cmx4m White P1	3000861
			Peha-haft Easy 8cmx4m White P1	3000871
			Peha-haft Easy 6cmx4m White P1	3000880
			Peha-haft Easy 8cmx4m White P1	3000890
			DermaPlast easy-rip 2.5cmx4m White P1	3000900
			Dermaplast easy-rip 4cmx4m White P1	3000910
			Dermaplast easy-rip 6cmx4m White P1	3000920
			Peha-haft Easy 6cmx4m Blue P1	3100800
			Peha-haft Easy 8cmx4m Blue P1	3100810
			Dermaplast easy-rip 8cmx4m White P1 CH	3001400
			Dermaplast easy-rip 6cmx4m Blue P1 CH	3001410
			Dermaplast easy-rip 8cmx4m Blue P1 CH	3001420

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.

