

## 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

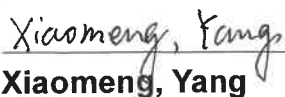
We hereby declare that the above mentioned products with CE marking meet the provisions of Regulation (EU) 2017/745 of the European Parliament and of the

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. 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):2021.06.04**

## Statement about EU Declaration of Conformity

We

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, Shenzhen, China

Hereby

Declare that

The Non-woven products with information in the table below are covered by the product name:

**Nonwoven Cohesive Bandage** on

EC-Declaration of Conformity:

**WN-CE(MDR) 27-13 EU DoC of Non-sterile Bandage and Tape product A0**

that we issue, which can be placed in the market as a medical device according to MDR 2017/745.

REF	Supplier identification number	Material description
3000840	603-016119	Peha-haft Easy 6cm x 4m White P1
3000850	603-016115	Peha-haft Easy 8cmx4m White P1
3000860	603-016120	Peha-haft Easy 6cmx4m White P1
3000870	603-016113	Peha-haft Easy 8cmx4m White P1
3000880	603-016112	Peha-haft Easy 6cmx4m White P1
3000890	603-016116	Peha-haft Easy 8cmx4m White P1
3000900	603-016118	DermaPlast easy-rip 2.5cmx4m White P1
3000910	603-016117	Dermaplast easy-rip 4cmx4m White P1
3000920	603-016122	Dermaplast easy-rip 6cmx4m White P1
3100800	603-016121	Peha-haft Easy 6cmx4m Blue P1
3100810	603-016114	Peha-haft Easy 8cmx4m Blue P1

Signature: 

Date: 2023.08.23

Name and Position: Minny Liu (RA Engineer)

Winner Medical Co., Ltd.