

## EC DECLARATION OF CONFORMITY

### Manufacturer:

Name: Changzhou Hualian Health Dressing Co., Ltd.

Add: No.55 Yuejin Road, Zouqu Town, Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

### European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

**Product Name:** Medical Tape

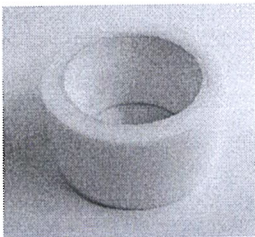
**Model:** A-Nonwoven, B-Silk, C-PE, D-Cotton

**Size:** 1.25cm × 457cm, 2.5cm × 457cm, 5.0cm × 457cm, 7.5cm × 457cm, 10.0cm × 457cm, 1.25cm × 914cm, 2.5cm × 914cm, 5.0cm × 914cm, 7.5cm × 914cm, 10.0cm × 914cm, 30.48cm × 914cm, 1.25cm × 1371cm, 2.5cm × 1371cm, 5.0cm × 1371cm, 1.25cm × 500cm, 2.5cm × 500cm, 5.0cm × 500cm, 7.5cm × 500cm, 10.0cm × 500cm, 1.25cm × 1000cm, 2.5cm × 1000cm, 5.0cm × 1000cm, 7.5cm × 1000cm, 10.0cm × 1000cm, 1.0cm × 1000cm, 1.0cm × 1300cm, 1.0cm × 2000cm

### Intended use:

It's intended to provide adhesive fix for wound dressings and bandages.

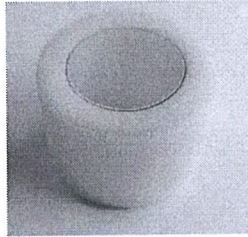
### Product Picture:



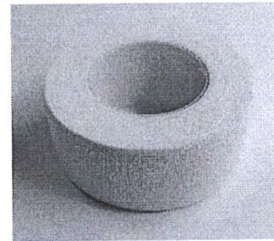
A-Nonwoven



B-Silk



C-PE



D-Cotton

**Risk Class of the Device:** The medical device has been assigned to class I, Rule 1 according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745.

**UMDNS code:** 13979

**UDI-DI:** 69417626002UX

**Standard:** /

**Conformity Assessment Route:** Self-declaration of Conformity

We herewith declare that the above-mentioned products meet the provisions of the following Medical Device REGULATION (EU) 2017/745. All technical documentations are retained under the promises of the manufacturer.

Changzhou Hualian Health Dressing Co., Ltd. is exclusively responsible for the declaration of conformity.

DIRECTIVES

**General applicable directives:**

Medical Device REGULATION (EU) 2017/745

**Notified Body:** /

**Identification Number:** /

**CE Certificate No.:** Not yet

Date CE mark was affixed: /

**Valid until:** /

Signature of issue person:

**Position:** Manager Representative

**Date:** 2021-01-12

**Name:** Huang Liqing

**Place:** Changzhou City, Jiangsu Province, China