

## 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

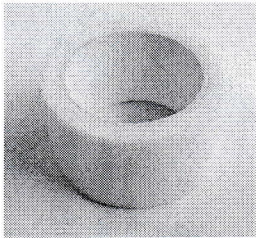
**Model:** A-Nonwoven, B-Silk, C-PE, D-Cotton

**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

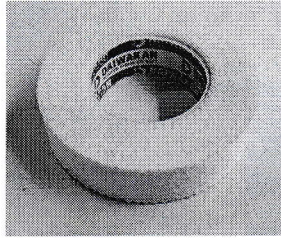
### Intended use:

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

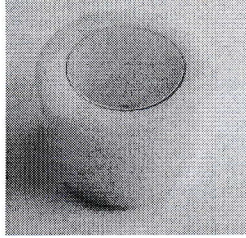
### Product Picture:



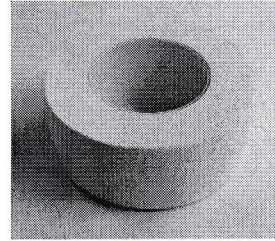
A-Nonwoven



B-Silk



C-PE



D-Cotton

### Product Reference number:

135300	135330
135312	135334
135320	135335
135321	135390
135323	135391
135324	135395
135325	135396
135326	135397
135327	135398
135328	1100105
135329	1100110

**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

Basic UDI-DI: 69417626002UX

Standard: /

Conformity Assessment Route: Annex II + Annex III

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:** /

**Signature of issue person:**

**Position:** Manager Representative

**Date:** 2021-01-12

**Valid until:**



**Name:** Huang Li qing

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