

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

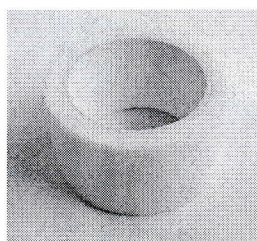
Model: A-Nonwoven, B-Silk, C-PE, D-Cotton

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

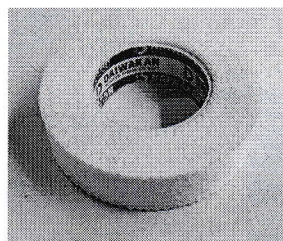
Intended use:

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

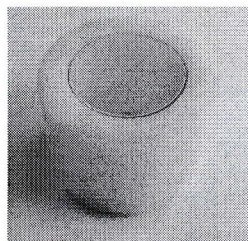
Product Picture:



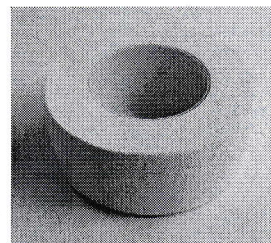
A-Nonwoven



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