

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: Self-adhesive Bandage

Model: A-Nonwoven, B-Cotton, C-Elastic fabric

Size/cm: 1cm×1000cm, 1cm×1300cm, 1cm×2000cm, 1.25cm×457cm, 1.25cm×500cm, 1.25×914, 1.25cm×1000cm, 1.25cm×1371cm, 2cm×1000cm, 2.5cm×450cm, 2.5cm×457cm, 2.5cm×500cm, 2.5cm×914cm, 2.5cm×1000cm, 2.5cm×1371cm, 3cm×250cm, 3.75cm×1350cm, 3.8cm×730cm, 3.8cm×910cm, 3.8×914cm, 3.8cm×1000cm, 3.8cm×1143cm, 3.8cm×1370cm, 5cm×250cm, 5cm×400cm, 5cm×457cm, 5cm×500cm, 5cm×914cm, 5cm×1000cm, 5cm×1371cm, 6cm×250cm, 7cm×400cm, 7.5cm×450cm, 7.5cm×500cm, 7.5cm×914cm, 7.5cm×1000cm, 8cm×250cm, 10cm×250cm, 10cm×450cm, 10cm×500cm, 10cm×914cm, 10cm×1000cm, 15cm×1000cm, 30cm×1000cm, 30.48cm×914cm

Intended use:

It's used to provide support and compress for a part of a patient's body or fixation for dressings.

Product Picture:



A-Nonwoven



B- Cotton



C- Elastic fabric

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: 10288

Basic UDI-DI: 69417626004V3

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

Valid until: /

Date CE mark was affixed: /

Signature of issue person: *Huang Liqing*

Position: Manager Representative

Date: 2021-01-20

Name: Huang Liqing

Place: Changzhou City, Jiangsu Province, China

