

Changzhou Hualian Health Dressing Co., Ltd CE Technical Documentation	Document No.: HL/CE-10-04	Edition: A0	Page: 1/1
	Declaration of Conformity	Effective Date: 2021-01-20	

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: 061007 / 061008 / 061009 / 061010 / 060906 / 060901 / 060922 / 060923 / 060924

Intended use:

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

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: 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: TÜV SÜD Product Service GmbH Zertifizierstellen

Ridlerstraße 65

80339 MÜNCHEN

Identification Number: 0123

CE Certificate No.: Not yet

Date CE mark was affixed: /

Valid until: /

Signature of issue person:

Position: Manager Representative

Date: 2021-01-20

