

EU 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

SRN: CN-MF-000021134

European representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

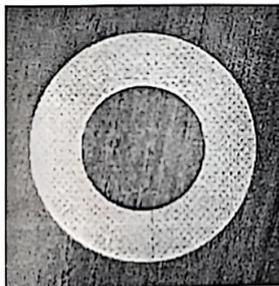
Product name: Medical Tape

Model: Type A, Type B, Type C

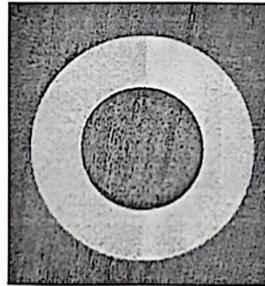
Size: 30mm×60mm、33mm×60mm、30mm×74mm、33mm×74mm

Intended use:

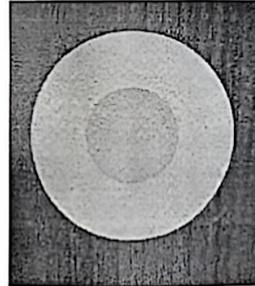
It's intended to fix other medical devices on specific sites of the human body.

Product picture:

Type A



Type B



Type C

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.

EMDN code: M050199

Basic UDI-DI: 69417626016VA

Conformity Assessment Route: Annex II, Annex III

CS reference: EN ISO 20417: 2021

EN ISO 15223-1: 2021

EN ISO 14971:2019/A11:2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2023

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

Notified body: /

CE identification number: /

CE

CE certificate No.: /

Valid from: 2024-08-25

Valid until: /

Signature: Huang Liqing
Name/Position: Huang Liqing
Management Representative



Date: 2024.08.25
Place: Changzhou City, Jiangsu Province

