



Changzhou Hualian Health
Dressing Co., Ltd.

CE Technical File

Document No: HL/CE-09-03

Edition: A/0

Page: 1/4


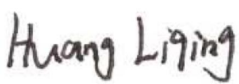

EU Declaration of Conformity


Effective Date: 2021-01-20

EU Declaration of Conformity of

Non-sterile Bandage

(according to Regulation (EU) 2017/745, Annex IV)

Prepared by		Reviewed by		Approved by	
Name	Li Chenmin	Name	Huang Liqing	Name	Gu Danjie
Date	2021.01.20	Date	2021.01.20	Date	2021.01.20
Signature		Signature		Signature	

	Changzhou Hualian Health Dressing Co., Ltd.	Document No: HL/CE-09-03	Edition: A/0	Page: 3/4
	CE Technical File	EU Declaration of Conformity	Effective Date: 2021-01-20	

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: Non-sterile Bandage

Model: /

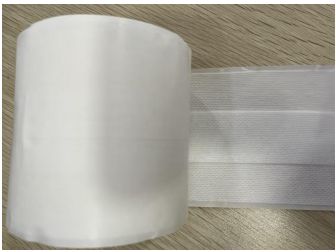
Size: 4cm×5m, 6cm×5m, 8cm×5m, 7cmx2cm,

Product code: 061501, 061502, 061503, 061105, 061205

Intended use:

It's intended for providing protection for minor superficial wound, absorbing the exudate.

Product picture:



Risk class of the device: The medical device has been assigned to Class I, Rule 4 according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745.

EMDN code: M04010101

Basic UDI-DI: 69417626009VD

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: 2013

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.



Changzhou Hualian Health
Dressing Co., Ltd.

CE Technical File

Document No: HL/CE-09-03

Edition: A/0

Page: 4/4

EU Declaration of Conformity

Effective Date: 2021-01-20

DIRECTIVES

Notified body: /

CE identification number: /



CE certificate No.: /

Valid from: 2021-01-20

Valid until: /

Signature: 

Date: 2021-01-20

Name/Position: Rita Zhu / GM

Place: Changzhou City, Jiangsu Province