

File Name: Declaration of conformity

File No: TCF-B-03

EC Declaration of Conformity

Manufacturer:

Wujiang City Shenlong Medical Health
Product Co., Ltd.
Gangzi Cun, Shenta, Lili Town, Wujiang
District, Suzhou, 215213 Jiangsu, China.
Tel: 0512-63290958 Fax: 0512-63290958

whose single Authorized Representative:

Caretechion GmbH
Niederrheinstr. 71
40474 Düsseldorf, Germany
DIMDI Code: DE/0000048026
Tel: +49 211 3003 6618 Fax: +49 211 3003 6619
Email: info@caretechion.com

We, the manufacturer, herewith declare that the products

Magnetic Ball Plasters

UMDNS-Code: 11374

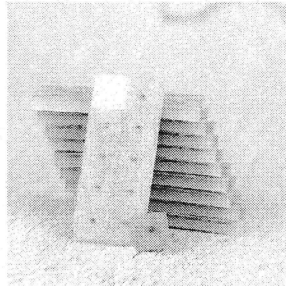
UDI-DI-Code:

Intended use:

Stick to the ear points of the human body for external stimulation. Non-invasive.

Product specifications: 24PCS, 50PCS, 100PCS

Product Picture:



Meet the provisions of MDR 2017/745 EU which apply to them.

The medical device has been assigned to class I according to Annex VIII of the MDR 2017/745 EU.



This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The product concerned has been manufactured under a quality management system according to Annex IX of MDR 2017/745 EU.

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/745 EU.

Applied harmonised standards, national standards or other normative documents:

EN 1041: 2008+A1:2013. EN ISO 10993-1: 2018. EN ISO 10993-5: 2009.

EN ISO 10993-10: 2013. EN ISO 14971: 2019. EN 62366-1:2015. EN ISO 15223-1:2016.

The above mentioned declaration of conformity is exclusively under the responsibility of

Wujiang City Shenlong Medical Health Product Co., Ltd.

Gangzi Cun, Shenta, Lili Town, Wujiang District, Suzhou, 215213 Jiangsu, China

Wujiang China 2021-06-28

Place, date

GM: 

Legally binding signature function

