

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer

Issuer:

Business Name: MATTI B.V.
Address: Van Galenlaan 11, 3931AL, Woudenberg, Netherlands

Manufacturer:

Business Name: MATTI B.V.
Address: Van Galenlaan 11, 3931AL, Woudenberg, Netherlands

Authorized Representative:

Business Name: APEX CE SPECIALISTS LIMITED
Address: UNIT 3D NORTH POINT HOUSE, NORTH POINT BUSINESS PARK, NEW MALLOW ROAD, CORK, T23 ATP
Country :

Product(s):

Name : Migraine Relief Cap
Brand: MW®
ASIN: 8720387823444

The medical device has been assigned to class I according to Appendix VIII of the Regulation (EU) 2017/745. Following the conformity assessment procedures relating to the Annex IX of Regulation (EU) 2017/734.



We declare that the product described above, which this declaration of conformity refers to, is in conformity with the relevant Union harmonization legislation:

- **Regulation MDR – 2017/745**

Through the technical standards/specifications specified below:

- **EN ISO 13485:2016**
- **EN ISO 14971:2019**
- **ISO 15223-1:2016**
- **ISO 10993-10:2010**
- **EN 1041:2008+A1:2013**
- **ISO 10993-1:2018**
- **ISO 10993-5:2009**

-Signed for and on behalf of:

APEX CE SPECIALISTS LIMITED
(Republic of Ireland)

Woudenberg, City – 2023-14-01
(place and date of issue)

Manager Matti, Dawoud
(name, function)

(signature)

This DoC compliance statement document is not authorized for commercial use.

