EC Declaration of Conformity

No. KK-CE-02-2.4

Manufacturer:

Koolcare Technology Co., Ltd
Add: No.6-10, A5, Shandong International Tech Park, South Waihuan Road, Linyi, 276017 Shandong, P.R.China
Facility: Wenlv Healthcare Park, No.18, Zhenbei Road, Xinyi city, 221400 Jiangsu, P.R.China

SRN: CN-MF-000017687

whose single Authorized EU-Representative:

Prolinx GmbH
Add: Brehmstr. 56, 40239 Düsseldorf Germany

SRN: DE-AR-000005129

We, the manufacturer, herewith declare that the products:

Heat Wraps

EMDN Code: Z120602
Basic UDI-DI: 697442359IWN08NY (8 hours model), 697442359IWN45P6 (12 hours model)
Heat Wrap Body 10PK UDI-DI: 06974423594009
Heat Wrap Neck 6PK UDI-DI: 06974423594016
Heat Wrap Belt 3PK UDI-DI: 06974423594023
Heat Wrap Body 5PK UDI-DI: 06974423593026
Heat Wrap Body 10PK UDI-DI: 06974423593033
Heat Wrap Body 30PK UDI-DI: 06974423593040
Heat Wrap Menstrual 5PK UDI-DI: 06974423593057
Heat Wrap Menstrual 10PK UDI-DI: 06974423593064
Heat Wrap Menstrual 30PK UDI-DI: 06974423593071

Intended use: Provides heat therapy for temporary relief of minor muscular and joint aches and pains associated with overexertion, strains, sprains and arthritis as well as back pain and other part cramps and strains .

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

The medical device has been assigned to class IIa according to Appendix VIII of the Regulation (EU) 2017/745. It bears the mark

CE 0197

following the conformity assessment procedures relating to the EC Declaration of Conformity set out in Annex IX of Regulation (EU) 2017/745.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration. We declare that the EU declaration of conformity is issued under the sole responsibility of ourselves. The product identified above complies with the general safety and performance requirements of the above EC regulation by meeting the following standards:

EN ISO 13485:2016；EN ISO 15223-1:2021; ISO 20417:2021；EN ISO 14971:2019；EN ISO 10993-1:2020；EN ISO 10993-5:2009；EN ISO 10993-10:2021；EN 62366-1:2015/A1:2020；MDR 2017/745

Registration No.: HZ 2159986-1

Notified body : **TÜV Rheinland LGA Products GmbH**
Address: Tillystraße 2, 90431 Nürnberg, Deutschland

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

Koolcare Technology Co., Ltd
No.6-10, A5, Shandong International Tech Park, South Waihuan Road, Linyi, 276017 Shandong, P.R.China

Xinyi 2026/03/20
Place, date

GAO WEIXIN / DR RC
Legally binding signature, Function