

EC Declaration of Conformity

Manufacturer:

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

Facility: Wenv 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:

Cold/hot pack

UMDNS-Code:12040

UDI-DI: 06974423590001

Model: 20g, 30g, 40g, 50g, 60g, 80g, 90g, 100g, 110g, 120g, 130g, 140g, 150g, 160g, 170g, 180g, 190g, 200g, 210g, 220g, 230g, 240g, 250g, 260g, 280g, 300g, 320g, 330g, 350g, 380g, 400g, 420g, 450g, 480g, 500g, 510g, 520g, 540g, 550g, 560g, 580g, 600g, 620g, 640g, 650g, 680g, 700g, 720g, 740g, 750g, 780g, 800g, 820g, 840g, 850g, 880g, 900g, 920g, 940g, 950g, 980g, 1000g, 1100g, 1200g, 1300g, 1400g, 1500g, 1600g, 1700g, 1800g, 1900g, 2000g, 2100g, 2200g, 2300g, 2400g, 2500g, 2600g, 2700g, 2800g, 2900g, 3000g, 3500g, 4000g, 4500g, 5000g, ect.

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

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



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.

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 10993-10:2013; EN 62366-1:2015/A1:2020; MDR 2017/745

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, China

Linyi, 2021/03/02
Place, date

Legally binding signature, Function

