

INTCO MEDICAL(HK) CO., LTD.

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG Tel:+86 511 83174088 Fax: +86 511 83174188 Website: www.intco.com.cn

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EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

INTCO Medical (HK) Co., Limited

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG Tel:+86 511 83174088

Fax: +86 511 83174188

MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster,

Germany Tel: +49-251-32266-0 Fax: +49-251-32266-22

We, the manufacturer, herewith declare that the products

Cold Packs

(HypaCool Instant Cold Pack, Instant Ice Pack Mini, Instant Plus Ice Pack, Instant Ice Pack, INSTANT COLD COMPRESS, HOT & COLD COMPRESS, Instant Soothe COLD pack, Cold Pack, Instant Freeze, Instant cold pack, Instant Cold Compress, cold pad, Instant Cool Pack, instant perineal cold pack,Cool Power Kompresse, Sofort Kaelte Kompresse, CoolPack Mini, CoolPack Midi, CoolPack Maxi)

Model codes

(CE0406,ICE0506,ICE0507,ICE0508,ICE0509,ICE1069,ICE0609,ICE0505,ICE1125,N14843,N14844, N14843-KUG,N14843-TED,N14844-KUG,N14844-TED,INSD,KID2,Q2281,F014,F014-1,S454008,VDA,3844, S454009,VDAA3942,751520-Q,751315-Q,T129525,007800,007909,09135,09136,100196.0,15510,151168, 122864,69710076,710,713,7710,18872,99228,99242,ICE1069,100695,WAL023,ICE0609,SAN-0024, ICE1420, PER613, ICE1719, CP201,CP202, ICE0408, 51003, 51004, 51005, 51006, 51006, 51007) *UMDNS Code*: **10932**

meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class $\rm~II~a$ according to Annex IX, Rule 9 of the Directive 93/42/EEC. It bears the mark

€ € 0197

The product concerned has been manufactured under a quality management system according to Annex V and Annex VII of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany Certificate No.: DD 2068388-1 Issue date: 11.09.2020 Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex VII of Directive 93/42/EEC.

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

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

Company: INTCO Medical (HK) Co., Limited

Address: FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG

en jiang 2020. 9. 30 Place , date

San Jui hua Legally binding signature, Function