Vivomed GmbH
Robert-Bosch-Straße 13-17
73312 Geislingen
Telefon 07331 – 2004 55
Email schweizer@vivomed.de

Erläuterung bzgl. Konformitätserklärung der Kälte-Sofortkompressen von

Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG
P.R. ChinaIntco

Die Konformitätserklärung (Anlage 1) läuft am 26.05.2024 offiziell aus. Aufgrund der Übergangsphase von der MDD zur MDR kann diese Konformitätserklärung formal nicht verlängert werden.

Die Verlängerung gilt deshalb nur im Zusammenhang folgender drei Dokumente:

- Abgelaufene Konformitätserklärung (Anlage 1)
- Ursprüngliches CE-Zertifikat (Anlage 2)
- TÜV-Bestätigung zur Verlängerung vom 8. Mai 2024 (Anlage 3).

Alle Dokumente sind immer im Zusammenhang zu verwenden.

Geislingen, 21.05.2024

Dr. Stephan Schweizer
QMB und Geschäftsführer Vivomed GmbH

Anlage 1

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

Document Number : CE-DC-001 Version: A/5

EC Declaration of Conformity

Manufacturer:

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

whose single Authorized Representative:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany
Tel: +49-251-32266-61
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 Compress,Cool Pack Mini,Cool Pack Midi,Cool Pack Maxi,Cold Compress）

Model codes

（T129525,Q2281,7710,713,710,ICE1069,151168,122864,INSD,N14843,N14844,09135,09136,007909,100196.0,99228,99242,ICE0609,ICE0506,ICE1125,ICE0505,751520-Q,751315-Q,KID2,122865,132935,HY-303,913-001,30649,193349.2,1130109,I114-15*23,I1114-13*15,04-018M,25.00200, 69710016）

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 Ⅱa according to Annex IX, Rule 9 of the Directive 93/42/EEC. It bears the mark

CE 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.

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

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

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

Zhenjiang Zhenjiang 2021.6.7
Place , date

Sun guihua Manager Sun guihua Manager
Legally binding signature, Function