



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:

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
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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,I114-13*15,04-018M,25.00200)

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



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.



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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
Place , date

Zhenjiang 2021.6.7

Sun guihua Manager

Legally binding signature, Function

Sun guihua Manager

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2068388-1

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

Products: Warmers, Cold Packs, Hot Packs
Aspects of manufacture concerned with securing and maintaining sterile conditions:
Disposable Surgical Masks, Disposable Surgical Gowns, Disposable Surgical Caps, Surgical Drapes
Replaces Approval, Registration No.: DD 60144577 0001

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15096008 012

Effective date: 2020-09-11

Expiry date: 2024-05-26

Issue date: 2020-09-11



Jason Pan
TÜVRheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2068388-1

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

The scope of certification also includes the following additional facilities:

No.	Location	Product groups manufactured
/01	Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Fengxian District, 201417 Shanghai P.R. China	Aspects of manufacture concerned with securing and maintaining sterile conditions of Disposable Surgical Masks, Disposable Surgical Gowns, Disposable Surgical Caps, Surgical Drapes
/02	Jiangsu Intco Medical Products Co., Ltd. No. 77 Yandunshan Road, Dagang Zhenjiang 212132 Jiangsu P.R. China	Warmers, Cold Packs, Hot Packs

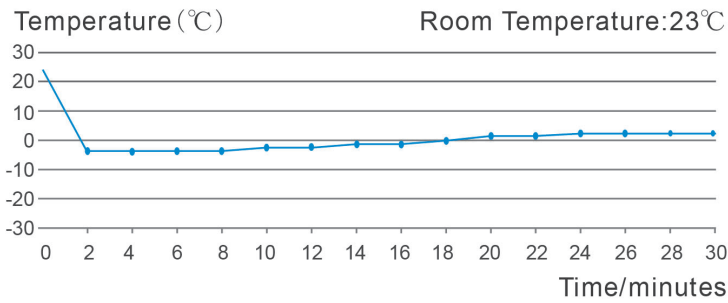
Report No.: 15096008 012
Effective date: 2020-09-11
Expiry date: 2024-05-26
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Instant Cold Pack



First Aid/Sports Support/Home Care.

External application only.

For relief of pain and swelling caused by sprains, strains, contusions, minor burns, toothaches and insect bites.

This product can be customized in accordance with any sample size.

Item Number	ICE 0506	ICE 0609
Description	12.7*15.3CM	15.3*22.9CM
Weight	109G	237G
Material	PE&NYLON	PE&NYLON

Characteristic:

Single use cold application without the drippy mess of ice cubes.

Needs no refrigeration, convenient and portable.

Primary usage for outdoor activity injuries and first aid.

Usage:

Locate inner pouch. Squeeze firmly to rupture inner fluid pouch.

Shake briefly to mix contents.

Wrap in soft cloth and apply.

Best if activated between 32 and 80 degrees fahrenheit.

