

## ICE PACK SOFT-GHIACCIO ISTANTANEO TNT

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### Dati normativi

**Fabbricante:** INTCO MEDICAL (HK) CO., LTD. FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG; operatore certificato da TUV Rheinland secondo la norma EN ISO 13485:2016 Dispositivi medici – Sistemi di gestione per la qualità

**Distributore esclusivo:** Fisiosviluppi s.r.l.

**Classificazione CND:** M9001 – DISPOSITIVI CRIOTERAPICI E TERMOTERAPICI

**Classe di rischio D.M. :** IIa

**Numero di Repertorio (RDM):** 2420772

**Riferimenti e norme:** il prodotto è un dispositivo medico marcato CE, secondo il REGOLAMENTO (UE) 2017/745.

**Confezionamento:** scatola di cartone da 25 buste

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## Scheda prodotto



# Ice pack soft

## Ghiaccio istantaneo tnt

Ghiaccio istantaneo monouso, da usare in tutti i casi in cui necessiti la crioterapia e l'uso del freddo. Il materiale della busta assicura un piacevole contatto con le parti sensibili del corpo (es. viso).

### UTILIZZO

Il freddo terapeutico riduce il flusso sanguigno nella zona interessata, contribuendo a ridurre l'infiammazione e il gonfiore. Inoltre, il freddo può agire come un analgesico naturale, alleviando il dolore e fornendo un senso di comfort. Indicato per alleviare il dolore e il gonfiore causati da:

- Distorsioni
- Stiramenti
- Contusioni
- Ustioni minori
- Mal di denti
- Punture di insetti



### CARATTERISTICHE

Contatto soffice con la pelle grazie al materiale in TNT della busta

Subito pronto all'uso dopo semplice attivazione

Conformabile ai diversi siti di applicazione

### COMPOSIZIONE

Acqua, urea, TNT (testato per il contatto con la pelle)

CODICE PRODOTTO	Formato	Peso	Confezionamento	Smaltimento
ST-IP250S	Busta 14x18 cm	250 g	Cartone da 25 buste, pedana da 73 cartoni (1.825 buste)	Residuo secco-indifferenziato (seguire indicazioni Comune di appartenenza)

## Busta con istruzioni per l'uso ed etichetta

**IT-ATTENZIONE:** Non congelare. Non applicare su cute lesa. Non utilizzare su pazienti con problemi sensoriali. Prima dell'uso conservare a temperatura ambiente. Lo stocaggio a temperature inferiori potrebbe causare congelamento dopo l'attivazione. Conservare in un luogo asciutto.

**AVVERTENZE:** tenere fuori dalla portata dei bambini. Nocivo se ingerito. In caso di ingestione accidentale, contattare immediatamente il centro antiveneni o un medico. Non forare la borsa esterna. Se la sacca si rompe e il fluido viene a contatto con la pelle o gli occhi, sciacciare immediatamente con acqua e chiamare un medico. Non mescolare con materiali combustibili.

**CONTENUTO:** Urea, acqua

**EN-CAUZION:** Do not freeze the bag. Do not use on injured skin. Do not use on sensory impaired patients. Prior to use store at room temperature. Storage at lower temperatures could cause frostbite after activation. Store in a dry place.

**WARNINGS:** keep out of reach of children. Harmful if swallowed. If accidentally swallowed contact poison control center or physician immediately. Do not puncture outer bag. If bag breaks and fluid contacts skin or eyes flush with water immediately and call physician. Do not mix with combustible materials.

**CONTAINS:** Urea, water

**ES-PRECAUDIÓN:** No congelar la bolsa. No utilizar sobre piel lesionada. No utilizar en pacientes con problemas sensoriales. Antes de su uso, conservar a temperatura ambiente. El almacenamiento a temperaturas más bajas podría causar congelación después de la activación. Almacenar en lugar seco.

**ADVERTENCIAS:** mantener fuera del alcance de los niños. Nocivo por ingestión. En caso de ingestión accidental, contactar inmediatamente con un centro de toxicología o un médico. No perforar la bolsa exterior. Si la bolsa se rompe y el líquido entra en contacto con la piel o los ojos, lavar inmediatamente con agua y llamar al médico. No mezclar con materiales combustibles.

**CONTIENE:** Urea, agua

**FR-ATTENTION :** Ne pas congelé le sachet. Ne pas utiliser sur une peau lésée. Ne pas utiliser sur des patients souffrant de troubles sensoriels. Avant utilisation, conserver à température ambiante. Le stockage à des températures inférieures pourrait provoquer des gélifications après l'activation. Stocker dans un endroit sec.

**AVERTISSEMENTS :** garder hors de portée des enfants. Nocif en cas d'ingestion. En cas d'ingestion accidentelle, contacter immédiatement le centre antipoison ou un médecin. Ne pas percer le sac extérieur. Si le sac se brise et que le liquide entre en contact avec la peau ou les yeux, rincer immédiatement à l'eau et appeler un médecin. Ne pas mélanger avec des matériaux combustibles.

**CONTENU :** Urea, eau

**DE-VORSICHT:** Den Beutel nicht einfrieren. Nicht auf verletzter Haut verwenden. Nicht bei sensorisch eingeschränkten Patienten anwenden. Vor der Anwendung bei Raumtemperatur lagern. Die Lagerung bei niedrigeren Temperaturen kann nach der Aktivierung zu Erfrierungen führen. An einen trockenen Ort lagern.

**WARNING:** Außerhalb der Reichweite von Kindern aufbewahren. Gesundheitsschädlich bei Verschlucken. Bei versehentlichem Verschlucken sofort Giftnotzentrale oder Arzt verständigen. Außenbeutel nicht durchstechen. Wenn Beutel reift und Flüssigkeit mit Haut oder Augen in Berührung kommt, sofort mit Wasser spülen und Arzt rufen. Nicht mit brennbaren Materialien mischen.

**ENTHÄLT:** Harnstoff, Wasser

**INTCO MEDICAL(HK) CO., LTD.**  
Flat/FRM 19C, Lockhart Centre,  
301-307 Lockhart Road,  
Wan Chai, Hong Kong  
Made in PRC

**EC REP:** MedNet EC-REP GmbH  
Borkstrasse 10,  
48163 Münster  
Germany

## Dichiarazione di Conformità



### 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](http://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  
 Fax: +86 511 83174188

**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, CoolPack Mini, Cool Pack Midi, Cool Pack Maxi, Cold Compress, Ice Pack - Ghiaccio istantaneo , Ghiaccio istantaneo TNT

#### Model codes

(T129525,Q2281,7710,713,710,ICE1069,151168,122864,INSD,N14843,N14844,09135,09136,007909,100196,0,99228,99  
 242,ICE0609,ICE0506,ICE1125,ICE0505,751520-Q,751315-Q,KID2,122865,132935,HY-303,913-001,30649,193349,2,113  
 0109,I114-15\*23,I1114-13\*15,04-018M,25.00200,Q2281PK288 , ST-IP250 , ST-IP250S )

*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



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

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**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](http://www.intco.com.cn)

produced devices.

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

Company: **INTCO Medical (HK) Co., Limited**

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

Zhenjiang  
Place , dateZhenjiang 2022.2.11Junguihua Manager  
Legally binding signature, Function

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## Certificato CE

## 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. ChinaProducts: 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

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

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## 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

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