

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60087401 0001

Report No.: 15044656 003

Manufacturer: Intco Medical (HK) Co., Limited
Unit 04, 7/F Bright Way Tower
No. 33 Mong Kok Rd.
KL
Hong Kong

Products: Medical Devices

(see attachment for products and additional sites)

Replaces Approval, Registration No.: DD 60038675 0001

Expiry Date: 2016-08-21

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.

Effective Date: 2013-11-04

Date: 2013-11-04



Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60087401 0001
Report No.: 15044656 003

Manufacturer: Intco Medical (HK) Co., Limited
Unit 04, 7/F Bright Way Tower
No. 33 Mong Kok Rd.
KL
Hong Kong

Products:

- Warmers
- Cold Packs
- Hot Packs
- Hot/Cold Packs

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Disposable Surgical Masks
- Disposable Surgical Gowns
- Disposable Surgical Caps
- Surgical Drapes

Date: 2013-11-04



Notified Body

X Ren

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60087401 0001
Report No.: 15044656 003

Manufacturer: Intco Medical (HK) Co., Limited
Unit 04, 7/F Bright Way Tower
No. 33 Mong Kok Rd.
KL
Hong Kong

Sites included:

Shanghai Intco Medical Supply Co., Ltd.
No. 1358, Hubin Road, Fengxian District
Shanghai 201417, P. R. China

Manufacture of Warmers, Cold Packs, Hot Packs, Hot/Cold
Packs

INTCO (Zhenjiang) Machinery Co., Ltd.
No. 77 Yandunshan Road, Dagang Zhenjiang,
Jiangsu Province 212132, China

Manufacture of Warmers, Cold Packs, Hot Packs, Hot/Cold
Packs

Date: 2013-11-04



Notified Body

X. Ren