

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

**Registration No.:** DD 60144577 0001

**Report No.:** 15096008 008

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

**Products:** Medical Devices  
  
(see attachment for products and additional sites included)  
  
Replaces Approval, Registration No.: DD 60113159 0001

**Expiry Date:** 2021-08-21

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:** 2020-08-25

**Date:** 2020-08-25

Notified Body

Herbert Zhong



**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**

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**Report No.:** 15096008 008

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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

**Date:** 2020-08-25

**Notified Body**

**Herbert Zhong**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
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FLAT/RM 19C, LOCKHART CENTRE  
301-307 LOCKHART ROAD, WAN CHAI  
HONG KONG  
P.R. China

**Sites included:**

Shanghai Intco Electrode Manufacturing Co., Ltd.  
No. 1358, Hubin Road, Fengxian District,  
Shanghai 201417, China

Aspects of manufacture concerned with securing and  
maintaining sterile conditions of Disposable Surgical Masks,  
Disposable Surgical Gowns, Disposable Surgical Caps,  
Surgical Drapes

Jiangsu Intco Medical Products Co., Ltd.  
No. 77 Yandunshan Road, Dagang, Zhenjiang,  
Jiangsu Province 212132, China

Warmers, Cold Packs, Hot Packs

**Date:** 2020-08-25

**Notified Body**

**Herbert Zhong**

