

# 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  
TÜV Rheinland LGA Products GmbH  
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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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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

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