

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

A circular stamp of TÜVRheinland LGA Products GmbH with a signature over it. The signature is in blue ink and reads "Jason Pan".

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.

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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

Report No.: 15096008 012

Effective date: 2020-09-11

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A circular stamp of TÜV Rheinland LGA Products GmbH is shown, with a signature "Jason Pan" written over it. Below the stamp, the text "Jason Pan" and "TÜV Rheinland LGA Products GmbH" are printed, followed by the address "Tillystraße 2 · 90431 Nürnberg · Germany".

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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