## **EC** Certificate



## Full Quality Assurance System MDD Annex II excl. 4

Registration No.:

HD 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:

Disposable Electrosurgical Active Electrodes (Disposable Electrosurgical

Pencils), Disposable Patient Plates (Grounding Pads) Replaces Approval, Registration No.: HD 60144580 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 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 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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TÜVRheinland

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FLAT/RM 19C, LÓCKHART CENTRE, 301-307 LOCKHART ROAD,

WAN CHAI, HONG KONG,

P.R. China

No. Location

/01

Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Fengxian District, 201417 Shanghai P.R. China Product groups manufactured

Disposable Electrosurgical Active Electrodes (Disposable Electrosurgical Pencils), Disposable Patient Plates (Grounding Pads)

Report No.:

15096008 012

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