

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

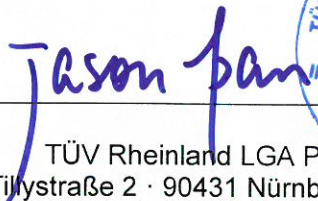

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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


The seal is circular with the text 'TÜV Rheinland LGA Products GmbH' around the top and 'Zertifizierungsstelle' around the bottom. In the center is the TÜVRheinland logo.
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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:

No.	Location	Product groups manufactured
/01	Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Fengxian District, 201417 Shanghai P.R. China	Disposable Electrosurgical Active Electrodes (Disposable Electrosurgical Pencils), Disposable Patient Plates (Grounding Pads)

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