

Certificate

Quality Management System EN ISO 13485:2016

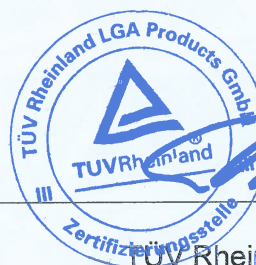
Registration No.: SX 2068388-1

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

Scope: Design and Development, Manufacture and Distribution of Disposable
Electrosurgical Active Electrodes (Disposable Electrosurgical Pencils),
Disposable Patient Plates (Grounding Pads), Disposable
Electrocardiograph Electrodes (Disposable ECG Electrodes), Scooter;
Manufacture and Distribution of Disposable Surgical Masks, Disposable
Surgical Gowns, Disposable Surgical Caps, Surgical Drapes, Tab
Electrodes, Electrocardiograph Electrode Stud Sets (ECG Electrode Stud
Sets), Transcutaneous Electrical Nerve Stimulation Electrodes (TENS
Electrodes), Repositionable Electrodes;
Manufacture of Manual Wheelchairs, Electric Wheelchairs, Intravenous
Injection Poles (IV Poles), Cold Packs, Hot Packs, Hot/Cold Packs,
Warmers, Cooling Patches, Cool Gel Mats, Hot Cold Pads, Gel Beads, Ice
Bags, Examination Gloves, Commode Chairs, Rollators, Canes &
Walkers, Shower Chairs, Overbed Tables, Patient Lifts, Infant Heel
Warmers, Cool Scarfs, Hot Water Bags, Isolation Gowns, Medical Caps,
Disposable Electrocardiograph Electrodes (Disposable ECG Electrodes),
Shoe Covers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244448125-200
Effective date: 2022-12-16
Expiry date: 2025-12-15
Issue date: 2022-12-15



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Intco Medical (HK) Co., Limited FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG, P.R. China	License holder only
/02	c/o Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Fengxian District, 201417 Shanghai P.R. China	Design and Development, Manufacture and Distribution of Disposable Electrosurgical Active Electrodes (Disposable Electrosurgical Pencils), Disposable Patient Plates (Grounding Pads), Disposable Electrocardiograph Electrodes (Disposable ECG Electrodes); Manufacture and Distribution of Disposable Surgical Masks, Disposable Surgical Gowns, Disposable Surgical Caps, Surgical Drapes, Tab Electrodes, Electrocardiograph Electrode Stud Sets (ECG Electrode Stud Sets), Transcutaneous Electrical Nerve Stimulation Electrodes (TENS Electrodes), Repositionable Electrodes

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

The scope of certification also covers the following:

/03 c/o Jiangsu Intco Medical Products Co.,
Ltd.
No. 77 Yandunshan Road,
Dagang
Zhenjiang
212132 Jiangsu
P.R. China

Design and Development, Manufacture and
Distribution of Scooter;

Manufacture of Manual Wheelchairs, Electric
Wheelchairs, Intravenous Injection Poles (IV
Poles), Cold Packs, Hot Packs, Hot/Cold
Packs, Warmers, Cooling Patches, Cool Gel
Mats, Hot Cold Pads, Gel Beads, Ice Bags,
Examination Gloves, Commode Chairs,
Rollators, Canes & Walkers, Shower
Chairs, Overbed Tables, Patient Lifts, Infant
Heel Warmers, Cool Scarfs, Hot Water Bags,
Isolation Gowns, Medical Caps, Disposable
Electrocardiograph Electrodes (Disposable
ECG Electrodes), Shoe Covers

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