EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60147884 0001

Report No.: 17058319 008

Manufacturer:
COPPER MEDICAL TECHNOLOGY
CO., LTD.
Factory Building B1 (101-201)
Glory Industrial Factory Zone
No. 2 Baolong 5 Road, Longgang
518116 Shenzhen
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60112493 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2020-07-01

Date: 2020-07-01

Notified Body

Jing Zhang

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147884 0001
Report No.: 17058319 008

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Products:

- Percutaneous Nephrostomy Sets
- Ureteral Stent Sets
- Introducer Sets
- Disposable Pressure Transducers
- Angiographic Syringes
- Drainage Catheter Sets
- Ureteral Access Sheaths
- Guide Wires

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Balloon Inflation Devices
- Dose-Control Syringes
- Bladder Irrigators
- Hemostasis Valve Sets

Notified Body

Date: 2020-07-01

Jing Zhang

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle