

EC Certificate

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

Registration No.: HD 60120141 0001

Report No.: 17056756 002

Manufacturer: Life Medical Equipment

(Guangzhou) Co., Ltd.

5th floor, 13th building Julong

industrial Zone

827 Xicha Road, Baiyun district

Guangzhou

510407 Guangdong

China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60110397 0001

Expiry Date: 2021-06-29

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: 2017-10-31

Date: 2017-10-31

Notified Bodyster 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.



Doc. 1/1, Rev.0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

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Report No.: 17056756 002

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Products:

- Arterial Venous (A.V.) Cannulas
- Tracheobronchial Tube Kits
- Enteral Feeding Tubes
- Enteral Feeding Sets

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Needleless Adapters
- Stopcocks
- IV Infusion Sets
- Extension Sets
- Decompression Pads

Date: 2017-10-31

