

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

Registration No.: HD 60092650 0001

Report No.: 17038049 001

Manufacturer: Bain Medical Equipment
(Guangzhou) Co., Ltd.
No. 10, Juncheng Road,
Eastern Area, Economic and
Technological Development District
Guangzhou 510760
China

Products: Medical Devices

(see attachment for products and additional site included)

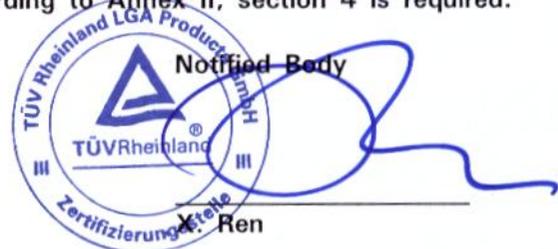
Replaces Approval, Registration No.: HD 60035006 0001

Expiry Date: 2019-05-14

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: 2014-05-15

Date: 2014-05-15



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60092650 0001
Report No.: 17038049 001

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(Guangzhou) Co., Ltd.
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Guangzhou 510760
China

Products:

Disposable A.V. Fistula Needle Sets, Tubing Sets
for Hemodialysis, Tubing Sets for Blood
Purification, Hemodialyzers;

Aspects of manufacture concerned with securing and
maintaining sterile conditions: Drain Bags,
Disposable Hemodialysis Care Kits

Site included:

No. 10 BanHe Road, LuoGang District, Guangzhou,
510535, China

Manufacture of Hemodialyzers

Date: 2014-05-15

