EC Certificate

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

Registration No.: HD 60133038 0001

Report No.: 16806267 006

Manufacturer:

Beijing Aerospace
Changfeng Co., Ltd.
CASNUC Building, No. 51-A,
Yongding Road, Haidian District
100039 Beijing
China

Products:

Medical devices

(see attachment for site and products included)

Replaces Certificate, Registration no.: HD 60130281 0001

Expiry Date: 2023-07-11

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: 2019-11-07

Date: 2019-11-07

Notified Body

Jing Zhang

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 60133038 0001
Report No.: 16806267 006

Manufacturer:
Beijing Aerospace
Changfeng Co., Ltd.
CASNUC Building, No. 51-A,
Yongding Road, Haidian District
100039 Beijing
China

Products:

- Anaesthetic Units
- Anaesthetic Vaporizers
- Ventilators
- Medical Ultrasound Diagnostic Systems

Site included:

Beijing Aerospace Changfeng Co., Ltd.
No.52 Yongding Road, Haidian District,
Beijing, 100039, China

Notified Body

Date: 2019-11-07

Jing Zhang