EC Certificate

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

Registration No.: HD 60130281 0001

Report No.: 16802111 006

Products: Medical devices

(see attachment for site and products included)

Replaces Certificate, Registration no.: HD 60124191 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: 2018-07-12

Date: 2018-06-13

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
Zertifizierungsstelle

S. Liu

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60130281 0001
Report No.: 16802111 006

Products:

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

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

Date: 2018-06-13

ACM PRODUCT SERIES

CE 0197

ACM812

Operation Manual