EC Certificate

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

Registration No.: HD 60144246 0001

Report No.: 17043095 009

Manufacturer:

Anntom Medica Limited
5/F, Building A6
Yinlong Industrial Zone
292 Shenshan Road, Longgang District
Shenzhen
518116 Guangdong
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60137594 0001

Expiry Date: 2024-05-27

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: 2019-12-02

Date: 2019-12-02

Notified Body

Fuxiu Sheng

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®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60144246 0001
Report No.: 17043095 009

Manufacturer:

Anntom Medica Limited
5/F, Building A6
Yinlong Industrial Zone
292 Shenshan Road, Longgang District
Shenzhen
518116 Guangdong
China

Products:

- Introducer Sets
- Angiographic Syringes

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Balloon Inflation Devices
- Manifolds
- Stopcocks
- Hemostasis Valve Sets

Date: 2019-12-02

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng