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.

Digitally signed by Perminov Andrei
Date: 2022.01.13 17:21:42 EET
Reason: MoldSign Signature
Location: Moldova

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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Introducer Sets, Angiographic Syringes, Balloon Inflation Devices, Manifolds, Stopcocks, Hemostasis Valve Sets

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-09-16
Certificate Registration No.:	SX 60137595 0001
An audit was performed. Report No.:	17043095 005
This Certificate is valid until:	2021-11-13

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-09-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Fuxiu Sheng

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