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 Iarovoi Petru
Date: 2021.01.11 09:05:57 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

2022-02-10

To Whom It May Concern,

This is to confirm that Recertification Audit for ISO 13485, Surveillance Audit for MDD was carried out on behalf of TÜV Rheinland LGA Product GmbH Notified Body (CE0197) as follows:

Applicant	:	Anntom Medica Limited
Address	:	5/F, Building A6, Yinlong Industrial Zone, 292 Shenshan Road, Longgang District, Shenzhen, 518116, Guangdong, P.R. China
Standards	:	EN ISO 13485:2016 MDD 93/42/EEC Annex II excluding (4)
Scope	:	Design and Development, Manufacture and Distribution of Introducer Sets, Angiographic Syringes, Balloon Inflation Devices, Manifolds, Stopcocks, Hemostasis Valve Sets
Date	:	2021-08-18~19
Report No.	:	10918965-100

It is recommend that the TÜV Rheinland LGA Products GmbH quality system certificate and TÜV Rheinland LGA Products GmbH Notified Body (0197) approval should remain valid under the condition, that the company implements suitable corrective actions for the non-conformities.

Yours sincerely,

Ms. Joanna HUANG

Joanna Huang
2022.02.13
21:30:16
+08'00'

Lead auditor

TÜV RHEINLAND (SHENZHEN) Co., Ltd.