

**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

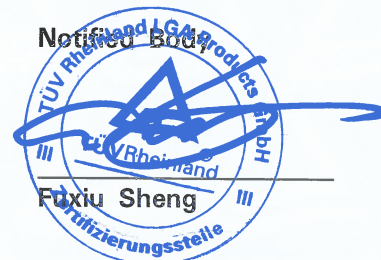
**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: HD 60137594 0001

**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



**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.

**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

