

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60149848 0001

**Report No.:** 17027664 016

**Manufacturer:** Shenzhen Boon Medical Supply  
Co., Ltd.  
No.18 Jirong Road,  
Shenkeng, Henggang Street  
Longgang District  
518173 Shenzhen  
P.R. China

**Products:** Sterile Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: DD 60148978 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-06-28

**Date:** 2020-06-28

Notified Body

Herbert Zhong



**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**

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**Attachment to  
Certificate**

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**Products:**

- Sterile High-pressure Angiographic Syringes for Single-use
- Sterile Syringes with Needle for Single-use
- Sterile Infusion Sets with Needle for Single-use
- Sterile Venous Blood Sampling Needles for Single-use
- Sterile Scalp Needles for Single-use
- Pressure Connecting Tubes for Single use

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

- Sterile Vaginal Dilators for Single-use
- Sterile Balloon Expansion Pressure Syringes for Single-use
- Single Use Laryngoscope Blades
- Sterile Infusion Connecting Tubes for Single-use

**Date:** 2020-06-28

**Notified Body**

**Herbert Zhong**

