# EC Certificate

## Directive 93/42/EEC Annex V
## Production Quality Assurance
## Medical Devices

TÜVRheinland®

**Registration No.:** DD 60139219 0001

**Report No.:** 15069281 008

**Manufacturer:**
Shanghai Everpure Medical Plastic
Co., Ltd.
No. 2418 Tingfeng Rd.
Xinnong Town, Jinshan District
201503 Shanghai
China

**Products:**
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60103727 0001

**Expiry Date:** 2024-05-27

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:** 2019-06-28

**Date:** 2019-06-28

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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®

Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** DD 60139219 0001
**Report No.:** 15069281 008

**Manufacturer:**
Shanghai Everpure Medical Plastic Co., Ltd.
No. 2418 Tingfeng Rd.
Xinnong Town, Jinshan District
201503 Shanghai
China

Products:

- Curettes
- Amnio-hooks
- Insufflation Tubing Sets

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Umbilical Cord Clamps
- Light Handle Covers
- Endoscopy Shaft Covers
- Sterile Dental Kits

Aspects of manufacture concerned with conformity of products with metrological requirements:

- Peak Meters

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-06-28