

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60134200 0001

**Report No.:** 15063533 014

**Manufacturer:** Yushin Medical Co., Ltd.  
36, Jomaru-ro 427beon-gil,  
Wonmi-gu, Bucheon-si,  
14558 Gyeonggi-do  
Republic of Korea

**Products:** Medical Devices  
  
(see attachment for products and additional site included)  
  
Replaces Approval, Registration No.: HD 60089264 0001

**Expiry Date:** 2023-11-20

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:** 2018-11-21

**Date:** 2018-11-20



**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**

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60134200 0001  
**Report No.:** 15063533 014

**Manufacturer:** Yushin Medical Co., Ltd.  
36, Jomaru-ro 427beon-gil,  
Wonmi-gu, Bucheon-si,  
14558 Gyeonggi-do  
Republic of Korea

Medical Sterile Tubings in Urology, Gastrology, Pneumology,  
Surgery, Neurosurgery and Anesthesiology:

- Silicone Foley Balloon Catheters
- Silicone Gastro-Duodenal Feeding Tubes (Levin)
- Silicone Tracheostomy Tubes
- Silicone Penrose Drain Tubes
- Silicone Wire-Reinforced Endotracheal Tubes
- Silicone Suprapubic Catheters
- Silicone Nephrostomy Catheters
- Silicone Endotracheal Tubes
- Disposable Ambulatory Infusion Pumps (Vessel Fuser)
- Silicone Clean Intermittent Catheterization Sets
- Extra Ventricular Drainage Catheter Systems
- Foley Balloon Catheter Kits
- Silicone Suprapubic Catheter Sets
- I.V. Valves
- Reusable Silicone Wire-Reinforced Endotracheal Tubes

Sterilization Method: Ethylene Oxide

**Date:** 2018-11-20



**Notified Body**

*M. Aihara*  
**M.Sc. M. Aihara**

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

Doc. 2/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60134200 0001  
**Report No.:** 15063533 014

**Manufacturer:** Yushin Medical Co., Ltd.  
36, Jomaru-ro 427beon-gil,  
Wonmi-gu, Bucheon-si,  
14558 Gyeonggi-do  
Republic of Korea

Medical Sterile Tubings in Urology, Gastrology, Pneumology,  
Surgery, Neurosurgery and Anesthesiology:

- Silicone Foley Balloon Catheters

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

- Drainage Circuits and Bag Sets
- Lee's Cerclage Balloons
- LockBand

Sterilization Method: Ethylene Oxide

Site included:

77, Jomaru-ro 385beon-gil, Wonmi-gu, Bucheon-si,  
Gyeonggi-do, 14557, Republic of Korea



**Notified Body**

**Date:** 2018-11-20

  
**M.Sc. M. Aihara**