



TÜVRheinland®

EC Certificate

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

Registration No.: HD 60142529 0001

Report No.: 16803454 010

Manufacturer: LEPU Medical Technology
(Beijing) Co. Ltd.
No.37 Chaoqian Road
Changping District
102200 Beijing
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60123024 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: 2019-09-06

Date: 2019-09-06

Notified Body



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 60142529 0001
Report No.: 16803454 010

Manufacturer: LEPU Medical Technology
(Beijing) Co. Ltd.
No.37 Chaoqian Road
Changping District
102200 Beijing
China

Products:

- High Pressure Extension Tubings
- Y-Hemostasis Valve Sets
- Angiography Control Syringes
- Contrast Medium Injection Manifold Kits
- PTA Balloon Dilatation Catheters
- Introducer Kits
- Inflation Device Kits (Y-Hemostasis Valve Sets and Inflation Devices)

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Radial Artery Compression Tourniquets
- Manifolds
- Needle-free Connectors
- Inflation Devices

Date: 2019-09-06

Notified Body

Jing Zhang

