

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2111879-1

Organization: LEPU Medical Technology (Beijing) Co., Ltd.
No.37 Chaoqian Road, Changping District,
102200 Beijing, P.R. China

Scope: Design and Development, Manufacture and Distribution of
High Pressure Extension Tubings, Y-Hemostasis Valve Sets,
Angiography Control Syringes, Contrast Medium Injection Manifold Kits,
PTA Balloon Dilatation Catheters, Introducer Kits, Coronary Stent Delivery
Systems, Inflation Device Kits (Y-Hemostasis Valve Sets and Inflation
Devices), Radial Artery Compression Tourniquets, Manifolds,
Needle-free Connectors and Inflation Devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 16803454 013

Effective date: 2020-09-11

Expiry date: 2023-09-10

Issue date: 2020-09-04

