

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Lepu Medical Technology
(Beijing) Co., Ltd.
No. 37 Chaoqian Road
Changping District
Beijing
Beijing
102200
China

乐普（北京）医疗器械股份有限公司
中国
北京
昌平区
超前路37号
邮编：102200

Holds Certificate No: **MD 616469**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Development, Manufacture and Distribution of Drug Eluting Coronary Stent Systems, PTCA and PTA Balloon Dilatation Catheters, Hydrophilic Guide Wires, Guiding Catheters and Extraction Catheters. Distribution of Valvuloplasty Balloon Catheters. Design and Manufacture of Prosthetic Heart Valves Accessories.

含药洗脱冠脉支架系统、冠状动脉和外周球囊扩张导管、超滑导丝、指引导管和血栓抽吸导管的设计、开发、制造和分销。瓣膜球囊导管的分销。机械心脏瓣膜附件的设计和制造。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-09-07

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