By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 616470**

Issued To: **Lepu Medical Technology (Beijing) Co., Ltd.**
No. 37 Chaoqian Road
Changping District
Beijing
102200
China

In respect of:

The design, development and manufacture of H-Stent™ Coronary Stent Systems, PTCA Balloon Dilatation Catheters, Hydrophilic Guide Wires and Guiding Catheters.

Digitally signed by Guțan Ghenadie
Date: 2022.01.06 13:58:42 EET
Reason: MoldSign Signature
Location: Moldova

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-06-24** Date: **2020-06-09** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 616470

Issued To:

Lepu Medical Technology (Beijing) Co., Ltd.
No. 37 Chaoqian Road
Changping District
Beijing
102200
China

Number	Device Name	Intended purpose per IFU
Class III		
---	Balancium Guide Wire	See CE 588780
---	ULTRASKIN™ Hydrophilic Guide Wires	See CE 616473
---	Mini Tadpole™ , Tadpole™ and NC Tadpole™ Coronary Dilatation Catheters	See CE 616474
---	Orien™ Guiding Catheter	See CE 619346
---	Hoper™ PTCA Balloon Dilatation Catheter	See CE 635784
---	H-Stent™ Coronary Stent Systems	See CE 646175

First Issued: **2015-06-24** Date: **2020-06-09** Expiry Date: **2024-05-26**

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 616470**
Date:	**2020-06-09**
Issued To:	**Lepu Medical Technology (Beijing) Co., Ltd.** **No. 37 Chaoqian Road** **Changping District** **Beijing** **102200** **China**

Subcontractor:	**Service(s) supplied**
Beijing Fengtai Yongding Disinfectant Equipment Factory Zhaoxindian#939, Fengtai District 100072 Beijing China	**ETO Sterilization**
Beijing Target Medical Technologies Inc. No.60, Shunren Rd Shunyi District Beijing, 101300 China	**ETO Sterilization**
Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36 8448 JB Heerenveen The Netherlands	**EU Representative**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616470**

Date: **2020-06-09**

Issued To: **Lepu Medical Technology (Beijing) Co., Ltd.**
No. 37 Chaoqian Road
Changping District
Beijing
102200
China

Date	Reference Number	Action
24 June 2015	8180409	First Issue.
27 July 2015	8374522	Scope amended to reflect range of products included.
27 November 2015	8365471	Scope extension to add "Ultracross™ PTA Balloon Dilatation Catheters".
17 March 2016	8467221	Scope extension to add "Hydrophilic Guide Wires".
13 April 2016	8212246	Scope extension to add "Guiding Catheters".
18 June 2016	8545869	The 13 April 2016 certificate history entry's Reference Number should be 8545869, replacing the DD SMO (8212246) that was originally used.
27 July 2016	8441080	Scope extension to add "H-Stent™ Stent Systems."
04 March 2019	8256575	Traceable to NB 0086.
Current	8953445	Certificate renewal and addition of product table. Removal of Ultracross PTA Balloon Dilatation Catheters from the scope. EU Representative address moved from Bolsward Netherlands to Heerenveen Netherlands. Addition of an alternative ETO Subcontractor - Beijing Fengtai Yongding Disinfectant Equipment Factory.