

# 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.**

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**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 616470

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Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
---	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

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

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

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**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**

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## Certificate History

Certificate No: **CE 616470**  
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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.

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