

EC Design-Examination Certificate

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

No.**CE 588780****Issued To:**

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

In respect of:**Balancium Guide Wire**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: 2016-06-24**Date: 2020-05-01****Expiry Date: 2022-06-27**

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

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.

EC Design-Examination Certificate

Supplementary Information to CE 588780

Issued To:

**Lepu Medical Technology
(Beijing) Co., Ltd.
No. 37 Chaoqian Road
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102200
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Device name: Balancium Guide wire

Intended purpose per IFU: It is indicated for use in the procedure for angiography to facilitate guidance and localization of the catheter and other interventional devices in coronary arteries and peripheral vascular system.

Classification: Class III

Catalogue Number	Length(cm)	Tip hardness(g)	Tip shape	Distal end structure
GW B185-0	185	0.6	straight	Core-to-tip
GW B185-0J	185	0.6	J	Core-to-tip
GW B300-0	300	0.6	straight	Core-to-tip
GW B300-0J	300	0.6	J	Core-to-tip
GW B185-1	185	1	straight	Core-to-tip
GW B185-1J	185	1	J	Core-to-tip
GW B300-1	300	1	straight	Core-to-tip
GW B300-1J	300	1	J	Core-to-tip
GW B185-2	185	2	straight	Core-to-tip

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Classification: Class III

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GW B185-2J	185	2	J	Core-to-tip
GW B300-2	300	2	straight	Core-to-tip
GW B300-2J	300	2	J	Core-to-tip
GW B185-S0	185	0.6	straight	Shaping ribbon
GW B185-S0J	185	0.6	J	Shaping ribbon
GW B300-S0	300	0.6	straight	Shaping ribbon
GW B300-S0J	300	0.6	J	Shaping ribbon
GW B185-S1	185	1	straight	Shaping ribbon
GW B185-S1J	185	1	J	Shaping ribbon

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Classification: Class III

Catalogue Number	Length(cm)	Tip hardness(g)	Tip shape	Distal end structure
GW B300-S1	300	1	straight	Shaping ribbon
GW B300-S1J	300	1	J	Shaping ribbon
GW B185-S2	185	2	straight	Shaping ribbon
GW B185-S2J	185	2	J	Shaping ribbon
GW B300-S2	300	2	straight	Shaping ribbon
GW B300-S2J	300	2	J	Shaping ribbon

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Certificate History

Date	Reference Number	Action
24 June 2016	10159700	First issue. Transfer from other Notified Body.
27 June 2017	10170687	Certificate renewal.
04 March 2019	8256575	Traceable to NB 0086.
19 December 2019	9785568	Change affecting Tyvek 1073B® packaging materials – all product codes are affected.
Current	8953775	Change of sterilization parameters. Addition of a new sterilization subcontractor "Beijing Fengtai Yongding Disinfectant Equipment Factory". Administrative change on product table.

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