

EC Design-Examination Certificate

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

No.**CE 616474****Issued To:**

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

In respect of:

Mini Tadpole™, Tadpole™ and NC Tadpole™ Coronary Dilatation Catheters

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: **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 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.

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Supplementary Information to CE 616474

Issued To:

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

Device name: Mini Tadpole and Tadpole Coronary Dilatation Catheter

Intended purpose per IFU:

They are indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
- Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction.
- Balloon Dilatation of a stent after implantation (balloon models 2.00mm – 4.00mm only)

Classification: Class III

Balloon Length (mm)	Balloon Diameter (mm)										
	Mini Tadpole™			Tadpole™							
	1.5	1.75	2.0	2.25	2.5	2.75	3.0	3.25	3.5	3.75	4.0
6	LPMRX 15006	LPMRX 17006	LPMRX 20006	LPCR 22006	LPCR 25006	LPCR 27006	LPCR 30006	LPCR 32006	LPCR 35006	LPCR 37006	LPCR 40006
8	LPMRX 15008	LPMRX 17008	LPMRX 20008	LPCR 22008	LPCR 25008	LPCR 27008	LPCR 30008	LPCR 32008	LPCR 35008	LPCR 37008	LPCR 40008
9	LPMRX 15009	LPMRX 17009	LPMRX 20009	LPCR 22009	LPCR 25009	LPCR 27009	LPCR 30009	LPCR 32009	LPCR 35009	LPCR 37009	LPCR 40009
10	LPMRX 15010	LPMRX 17010	LPMRX 20010	LPCR 22010	LPCR 25010	LPCR 27010	LPCR 30010	LPCR 32010	LPCR 35010	LPCR 37010	LPCR 40010
11	LPMRX 15011	LPMRX 17011	LPMRX 20011	LPCR 22011	LPCR 25011	LPCR 27011	LPCR 30011	LPCR 32011	LPCR 35011	LPCR 37011	LPCR 40011
12	LPMRX 15012	LPMRX 17012	LPMRX 20012	LPCR 22012	LPCR 25012	LPCR 27012	LPCR 30012	LPCR 32012	LPCR 35012	LPCR 37012	LPCR 40012
14	LPMRX 15014	LPMRX 17014	LPMRX 20014	LPCR 22014	LPCR 25014	LPCR 27014	LPCR 30014	LPCR 32014	LPCR 35014	LPCR 37014	LPCR 40014
15	LPMRX 15015	LPMRX 17015	LPMRX 20015	LPCR 22015	LPCR 25015	LPCR 27015	LPCR 30015	LPCR 32015	LPCR 35015	LPCR 37015	LPCR 40015
16	LPMRX 15016	LPMRX 17016	LPMRX 20016	LPCR 22016	LPCR 25016	LPCR 27016	LPCR 30016	LPCR 32016	LPCR 35016	LPCR 37016	LPCR 40016
17	LPMRX 15017	LPMRX 17017	LPMRX 20017	LPCR 22017	LPCR 25017	LPCR 27017	LPCR 30017	LPCR 32017	LPCR 35017	LPCR 37017	LPCR 40017
18	LPMRX 15018	LPMRX 17018	LPMRX 20018	LPCR 22018	LPCR 25018	LPCR 27018	LPCR 30018	LPCR 32018	LPCR 35018	LPCR 37018	LPCR 40018

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Device name: Mini Tadpole and Tadpole Coronary Dilatation Catheter

Intended purpose per IFU:

They are indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
- Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction.
- Balloon Dilatation of a stent after implantation (balloon models 2.00mm – 4.00mm only)

Classification: Class III

Balloon Length (mm)	Balloon Diameter (mm)										
	Mini Tadpole™			Tadpole™							
	1.5	1.75	2.0	2.25	2.5	2.75	3.0	3.25	3.5	3.75	4.0
20	LPMRX 15020	LPMRX 17020	LPMRX 20020	LPCR 22020	LPCR 25020	LPCR 27020	LPCR 30020	LPCR 32020	LPCR 35020	LPCR 37020	LPCR 40020
22	LPMRX 15022	LPMRX 17022	LPMRX 20022	LPCR 22022	LPCR 25022	LPCR 27022	LPCR 30022	LPCR 32022	LPCR 35022	LPCR 37022	LPCR 40022
23	LPMRX 15023	LPMRX 17023	LPMRX 20023	LPCR 22023	LPCR 25023	LPCR 27023	LPCR 30023	LPCR 32023	LPCR 35023	LPCR 37023	LPCR 40023
24	LPMRX 15024	LPMRX 17024	LPMRX 20024	LPCR 22024	LPCR 25024	LPCR 27024	LPCR 30024	LPCR 32024	LPCR 35024	LPCR 37024	LPCR 40024
25	LPMRX 15025	LPMRX 17025	LPMRX 20025	LPCR 22025	LPCR 25025	LPCR 27025	LPCR 30025	LPCR 32025	LPCR 35025	LPCR 37025	LPCR 40025
26	LPMRX 15026	LPMRX 17026	LPMRX 20026	LPCR 22026	LPCR 25026	LPCR 27026	LPCR 30026	LPCR 32026	LPCR 35026	LPCR 37026	LPCR 40026
30	LPMRX 15030	LPMRX 17030	LPMRX 20030	LPCR 22030	LPCR 25030	LPCR 27030	LPCR 30030	LPCR 32030	LPCR 35030	LPCR 37030	LPCR 40030
31	LPMRX 15031	LPMRX 17031	LPMRX 20031	LPCR 22031	LPCR 25031	LPCR 27031	LPCR 30031	LPCR 32031	LPCR 35031	LPCR 37031	LPCR 40031
32	LPMRX 15032	LPMRX 17032	LPMRX 20032	LPCR 22032	LPCR 25032	LPCR 27032	LPCR 30032	LPCR 32032	LPCR 35032	LPCR 37032	LPCR 40032
34	LPMRX 15034	LPMRX 17034	LPMRX 20034	LPCR 22034	LPCR 25034	LPCR 27034	LPCR 30034	LPCR 32034	LPCR 35034	LPCR 37034	LPCR 40034
38	LPMRX 15038	LPMRX 17038	LPMRX 20038	LPCR 22038	LPCR 25038	LPCR 27038	LPCR 30038	LPCR 32038	LPCR 35038	LPCR 37038	LPCR 40038

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Device name: NC Tadpole Coronary Dilatation Catheter

Intended purpose per IFU:

They are indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
- Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction.
- Balloon Dilatation of a stent after implantation (balloon models 2.00mm – 5.00mm only)

Classification: Class III

Balloon Length (mm)	Balloon Diameter (mm)											
	1.5	2.0	2.25	2.5	2.75	3.0	3.25	3.5	3.75	4.0	4.5	5.0
6	LPNRX15006	LPNRX20006	LPNRX22006	LPNRX25006	LPNRX27006	LPNRX30006	LPNRX32006	LPNRX35006	LPNRX37006	LPNRX40006	LPNRX45006	LPNRX50006
8	LPNRX15008	LPNRX20008	LPNRX22008	LPNRX25008	LPNRX27008	LPNRX30008	LPNRX32008	LPNRX35008	LPNRX37008	LPNRX40008	LPNRX45008	LPNRX50008
10	LPNRX15010	LPNRX20010	LPNRX22010	LPNRX25010	LPNRX27010	LPNRX30010	LPNRX32010	LPNRX35010	LPNRX37010	LPNRX40010	LPNRX45010	LPNRX50010
12	LPNRX15012	LPNRX20012	LPNRX22012	LPNRX25012	LPNRX27012	LPNRX30012	LPNRX32012	LPNRX35012	LPNRX37012	LPNRX40012	LPNRX45012	LPNRX50012
15	LPNRX15015	LPNRX20015	LPNRX22015	LPNRX25015	LPNRX27015	LPNRX30015	LPNRX32015	LPNRX35015	LPNRX37015	LPNRX40015	LPNRX45015	LPNRX50015
20	LPNRX15020	LPNRX20020	LPNRX22020	LPNRX25020	LPNRX27020	LPNRX30020	LPNRX32020	LPNRX35020	LPNRX37020	LPNRX40020	LPNRX45020	LPNRX50020
25	LPNRX15025	LPNRX20025	LPNRX22025	LPNRX25025	LPNRX27025	LPNRX30025	LPNRX32025	LPNRX35025	LPNRX37025	LPNRX40025	LPNRX45025	LPNRX50025
30	LPNRX15030	LPNRX20030	LPNRX22030	LPNRX25030	LPNRX27030	LPNRX30030	LPNRX32030	LPNRX35030	LPNRX37030	LPNRX40030	LPNRX45030	LPNRX50030

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Certificate History

Date	Reference Number	Action
24 June 2015	10149413	First issue.
10 March 2019	8256575	Traceable to NB 0086.
19 December 2019	9785568	Change affecting Tyvek 1073B® packaging materials – all product codes are affected.
01 May 2020	8953775	Change of sterilization parameters. Addition of a new sterilization subcontractor "Beijing Fengtai Yongding Disinfectant Equipment Factory". Administrative change on product table.
Current	9775839	Certificate Renewal. Removed 1.2mm Mini Tadpole balloon configurations. Removed 4.5mm and 5.0mm Tadpole balloon configurations.

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