EC Certificate

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TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2111879-1

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

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Lepu Medical Technology (Beijing) Co., Ltd. No.37 Chaoqian Road, Changping District, 102200 Beijing, P.R. China	High Pressure Extension Tubings, Y-Hemostasis Valve Sets, Angiography Control Syringes, Contrast Medium Injection Manifold Kits, PTA Balloon Dilatation Catheters, Introducer Kits, Inflation Device Kits(Y-Hemostasis Valve Sets and Inflation Devices), Radial Artery Compression Tourniquets, Manifolds, Needle-free Connectors, Inflation Devices.
/02	Lepu Medical Technology (Beijing) Co., Ltd. Building 5 & 6 No. 21 Courtyard, Panlong West Road, Pinggu District, 101204 Beijing, P.R. China	High Pressure Extension Tubings, Y-Hemostasis Valve Sets, Angiography Control Syringes, Contrast Medium Injection Manifold Kits, Inflation Device Kits (Y-Hemostasis Valve Sets and Inflation Devices), Radial Artery Compression Tourniquets, Manifolds, Needle-free Connectors, Inflation Devices

Report No.: 190132369 110

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2111879-1

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

Products: High Pressure Extension Tubings, Y-Hemostasis Valve Sets, Angiography Control Syringes, Contrast Medium Injection Manifold Kits, PTA Balloon Dilatation Catheters, Introducer Kits and Inflation Device Kits (Y-Hemostasis Valve Sets and Inflation Devices);
For the Following Medical Devices the Scope covers the Aspects of Manufacture concerned with Securing and Maintaining Sterile Conditions: Radial Artery Compression Tourniquets, Manifolds, Needle-free Connectors and Inflation Devices

Replaces Approval, Registration No.: HD 60142529 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

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EC Declaration of Conformity

Manufacturer

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

Whose single Authorized Representative:

Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB,
Heerenveen, the Netherlands
Tel: +31-515-573399; Fax: +31-515-760020

We, the manufacturer, herewith declare that the products

Brilliant ™ Introducer Kits
Model:As attached
UMDNS-Code: **10678** *GMDN-Code/Preferred Terms:* **P10678**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **Ⅱa** according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex Ⅱ of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 2111879-1
Issue date: 2021.05.25
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following the procedure relating to the EC Declaration of Conformity set out in Annex Ⅱ of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: LEPU Medical Technology (Beijing) Co. Ltd.
Address: No.37 Chaoqian Road,Changping District, Beijing,102200,P.R. China

Beijing/ 2021.08.07
Place, date

Bo Jiang/ QA Manager
Legally binding signature, Function

Models for Introducer Kits:

RSC040521-HS45-IC22-K-S, RSC040525-HS45-IC20-K-S, RSC040721-HS45-IC22-K-S,
RSC040725-HS45-IC20-K-S, RSC041121-HS45-IC22-K-S, RSC041125-HS45-IC20-K-S,
RSC041621-HS70-IC22-K-S, RSC041625-HS70-IC20-K-S, RSC042421-HS70-IC22-K-S,
RSC042425-HS70-IC20-K-S, RSC050521-HS45-IC22-K-S, RSC050525-HS45-IC20-K-S,
RSC050721-HS45-IC22-K-S, RSC050725-HS45-IC20-K-S, RSC051121-HS45-IC22-K-S,
RSC051125-HS45-IC20-K-S, RSC051621-HS70-IC22-K-S, RSC051625-HS70-IC20-K-S,
RSC052421-HS70-IC22-K-S, RSC052425-HS70-IC20-K-S, RSC060521-HS45-IC22-K-S,
RSC060525-HS45-IC20-K-S, RSC060721-HS45-IC22-K-S, RSC060725-HS45-IC20-K-S,
RSC061121-HS45-IC22-K-S, RSC061125-HS45-IC20-K-S, RSC061621-HS70-IC22-K-S,
RSC061625-HS70-IC20-K-S, RSC062421-HS70-IC22-K-S, RSC062425-HS70-IC20-K-S,
RSC070521-HS45-IC22-K-S, RSC070525-HS45-IC20-K-S, RSC070721-HS45-IC22-K-S,
RSC070725-HS45-IC20-K-S, RSC071121-HS45-IC22-K-S, RSC071125-HS45-IC20-K-S,
RSC071621-HS70-IC22-K-S, RSC071625-HS70-IC20-K-S, RSC072421-HS70-IC22-K-S,
RSC072425-HS70-IC20-K-S

RSC040521-HW45-IC22-K-S, RSC040525-HW45-IC20-K-S, RSC040721-HW45-IC22-K-S,
RSC040725-HW45-IC20-K-S, RSC041121-HW45-IC22-K-S, RSC041125-HW45-IC20-K-S,
RSC041621-HW70-IC22-K-S, RSC041625-HW70-IC20-K-S, RSC042421-HW70-IC22-K-S,
RSC042425-HW70-IC20-K-S, RSC050521-HW45-IC22-K-S, RSC050525-HW45-IC20-K-S,
RSC050721-HW45-IC22-K-S, RSC050725-HW45-IC20-K-S, RSC051121-HW45-IC22-K-S,
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RSC052421-HW70-IC22-K-S, RSC052425-HW70-IC20-K-S, RSC060521-HW45-IC22-K-S,
RSC060525-HW45-IC20-K-S, RSC060721-HW45-IC22-K-S, RSC060725-HW45-IC20-K-S,
RSC061121-HW45-IC22-K-S, RSC061125-HW45-IC20-K-S, RSC061621-HW70-IC22-K-S,
RSC061625-HW70-IC20-K-S, RSC062421-HW70-IC22-K-S, RSC062425-HW70-IC20-K-S,
RSC070521-HW45-IC22-K-S, RSC070525-HW45-IC20-K-S, RSC070721-HW45-IC22-K-S,
RSC070725-HW45-IC20-K-S, RSC071121-HW45-IC22-K-S, RSC071125-HW45-IC20-K-S,
RSC071621-HW70-IC22-K-S, RSC071625-HW70-IC20-K-S, RSC072421-HW70-IC22-K-S,
RSC072425-HW70-IC20-K-S

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.	SX 2111879-1
Certificate Holder	Lepu Medical Technology (Beijing) Co., Ltd. No.37 Chaoqian Road, Changping District, 102200 Beijing P.R. China
Scope	Design and Development, Manufacture and Distribution of High Pressure Extension Tubings, Y-Hemostasis Valve Sets, Angiography Control Syringes, Contrast Medium Injection Manifold Kits, PTA Balloon Dilatation Catheters, Introducer Kits, Coronary Stent Delivery Systems, Inflation Device Kits (Y-Hemostasis Valve Sets and Inflation Devices), Radial Artery Compression Tourniquets, Manifolds, Needle-free Connectors, Inflation Devices and Single-Use Syringe with Needle

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	190147236-110
Effective date	2023-09-11
Expiry date	2026-09-10
Issue date	2023-09-04

Replaces certificate SX 2111879-1 issued 2023-03-22

This certificate can be validated on https://www.certipedia.com

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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Certificate

Quality Management System
EN ISO 13485:2016

Registration No.	SX 2111879-1
Certificate Holder	Lepu Medical Technology (Beijing) Co., Ltd. No.37 Chaoqian Road, Changping District, 102200 Beijing P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Lepu Medical Technology (Beijing) Co., Ltd. No.37 Chaoqian Road, Changping District, 102200 Beijing P.R. China	Design and Development and Distribution of High Pressure Extension Tubings, Y-Hemostasis Valve Sets, Angiography Control Syringes, Contrast Medium Injection Manifold Kits, PTA Balloon Dilatation Catheters, Introducer Kits, Coronary Stent Delivery Systems, Inflation Device Kits (Y-Hemostasis Valve Sets a nd Inflation Devices), Radial Artery Compression Tourniquets, Manifolds, Needle-free Connectors, Inflation Devices and Single-Use Syringe with Needle;Manufacture of PTA Balloon Dilatation Catheters, Introducer Kits and Single-Use Syringe with Needle
/02	c/o Lepu Medical Technology (Beijing) Co. Ltd. Building 5, No. 21 Courtyard, Panlong West Road, Pinggu District, 101204 Beijing P.R. China	Manufacture of High Pressure Extension Tubings, Y-Hemostasis Valve Sets, Angiography Control Syringes, Contrast Medium Injection Manifold Kits, Coronary Stent Delivery Systems, Inflation Device Kits (Y-Hemostasis Valve Sets and Inflation Devices), Radial Artery Compression Tourniquets, Manifolds, Needle-free Connectors, Inflation Devices

Report No.	190147236-110
Effective date	2023-09-11
Expiry date	2026-09-10
Issue date	2023-04

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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must be completed with the company logo

LETTER OF AUTHORIZATION

Date: October 13th, 2023

To Whom It May Concern:

Hereby, we

Company Name: LEPU Medical Technology(Beijing)Co.,Ltd
Address: No.37 Chaoqian Road, Changping District, Beijing, China, 102200
Phone number: +86-10-80120666

Certify that:

Triumf Motiv SRL
Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1
Phone number: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand Brilliant™ Introducer kit in your country.

This letter of authorization remains valid for two years, starting from October 13.2023 and expiring on October 14, 2025.

Name: Jeff Yuan
Title: Regional sales manager
Signature: