Number: 6129534CE01

## **EU Quality Management System Certificate**

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

### Jiangsu Brightness Medical Devices Co., Ltd.

The 3rd floor of Building 3, Building 1 & Building 5-3, No. 66, Hehuan Road, Zhonglou Economic Development Area 213013 Changzhou, Jiangsu China

SRN ID.: CN-MF-000019184

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 6129535CN

Authorized Representative: Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB, Heerenveen The Netherlands

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

**DEKRA Certification B.V** 

B.T.M. Holtus Managing Director J.M. McKenzie

Principal Certification Manager

First Issued: 23 August 2023 Date: 23 August 2023 Expiry date: 1 August 2028

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 6129534CE01

# **EU Quality Management System Certificate**

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

LINEAR STAPLERS FOR VIDEOSURGERY (H020301, class llb)		
Device Name:		
Disposable Endocutter & Disposable Endocutter Reload	Intended Purpose: The Device is intended for use in	
	abdominal, thoracic, and gynaecologic surgery for	
	resection, transection, and creation of anastomosis.	

Conditions for or limitations to the validity of this certificate

N/A

#### **Certificate History**

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice	///Action///
	111111111111111111111111111111111111111	//////Reference//////////////////////////////////	///X//////////////////////////////////
0	23 August 2023	////6129535CN02//////	////first/issue/
1		//////////////////////////////////////	///////////////////////////////////////
2		//////////////////////////////////////	

First Issued: 23 August 2023 Date: 23 August 2023 Expiry date: 1 August 2028

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 www.dekra.nl Company registration 09085396



#### **EC** Certificate

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

Registration No.: HD 60143699 0001

Report No.: 15059498 012

Manufacturer: Jiangsu Brightness Medical Devices

Co., Ltd.

The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road Zhonglou Economic Development Area

Changzhou

213013 Jiangsu

P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60129487 0001

**Expiry Date:** 2023-06-04

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.

**Effective Date:** 2020-04-26

**Date:** 2020-04-26

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 9043 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC

TÜVRheinland

**Notified Body** 

concerning medical devices with the identification number 0197.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approva



# TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.: HD

HD 60143699 0001

Report No.: 15059498 012

Manufacturer: Jiangsu Brightness Medical Devices

Co., Ltd.

The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road Zhonglou Economic Development Area

Changzhou 213013 Jiangsu P.R. China

#### Products:

- Non-vascular Stents
- Disposable Endoscopic Ligating Loops
- Disposable Clip Appliers
- Disposable Veress Needles
- Disposable Endoscopic Retrieval Bags
- Disposable Suction and Irrigation Tubes
- Disposable Trocars
- Disposable Endoscopic Dissectors
- Skin Staplers and Removers
- Disposable Circular Staplers
- Disposable Hemorrhoids Staplers
- Disposable Linear Stapler and Reloads
- Disposable Linear Cutter Staplers and Reloads
- Disposable Curved Cutter Staplers
- Disposable Endocutters & Disposable Endocutter Reloads

Date: 2020-04-26

Herbert Zhong III



Jiangsu Brightness Medical Devices Co., Ltd.
The 3rd floor of Building 3, Building 1 & Building 5-3,
No.66, Hehuan Road, Zhonglou Economic
Development Area,
Changzhou, 213013 Jiangsu
China

Your ref. CA-22-7472936 Our ref. 6129535

Tel. +86 21 6056 7666
Fax +86 21 6056 7555
E-mail Xiaoli.ren@dekra.com

Shanghai, 2023-02-13

Subject: MDR certification status confirmation

To whom it may concern,

We, DEKRA certification BV, herewith confirm that DEKRA has accepted the application for Medical Device Regulation (EU 2017/745) ("MDR") certification of Disposable Endocutter & Disposable Endocutter Reload, Disposable Linear Cutter Stapler and Reload, Disposable Circular Stapler, Disposable Clip Appliers, Disposable Linear Stapler and Reload, Disposable Hemorrhoid Staplers from Jiangsu Brightness Medical Devices Co., Ltd. A Certification Agreement for the MDR conformity assessment has been signed between DEKRA and the legal manufacturer:

Jiangsu Brightness Medical Devices Co., Ltd.
The 3rd floor of Building 3, Building 1 & Building 5-3,
No.66, Hehuan Road, Zhonglou Economic Development Area,
Changzhou, 213013 Jiangsu
China

DEKRA is currently performing the Technical Documentation review of the Disposable Endocutter & Disposable Endocutter Reload (6129534-TDR01), Disposable Linear Cutter Stapler and Reload (6129536-TDR02), Disposable Clip Appliers (6129538-TDR03) for certification under the MDR. The review is at the date of this letter not yet completed and therefore no decision on the certification can be made yet.



2 MED/22-7472936

DEKRA has performed the Initial MDR certification audit at the legal manufacturer Jiangsu Brightness Medical Devices Co., Ltd. premises on: 12-16 December 2022 with the following audit scope and criteria:

- Initial audit MDR (EU)2017/745
- Initial audit EN ISO 13485:2016

During the audit 3 nonconformities were raised. The Corrective Action Plan as provided by the legal manufacturer following the audit nonconformities are under reviewing by the DEKRA audit team.

In addition to the above DEKRA will expressively mention to take art 7.3. of the general terms and conditions into consideration: *Unless DEKRA Certification has expressly granted the Other Party the right to use a certificate, certification mark and/or an attestation of conformity, the Other Party shall not in any manner suggest to third parties that there has been certification by DEKRA Certification.* 

On request of the competent authority of the manufacturer (or the competent authority of the authorized representative) DEKRA can confirm that:

- There were no potential safety related shortcomings identified by DEKRA during the last audit.
- DEKRA will inform Dutch competent authority about any significant safety-related shortcomings which are identified during the on-going conformity assessment.

With kind regards,

Xiaoli Ren

Project Manager DEKRA Certification BV



Address: The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road, Zhonglou Economic Development Area, Changzhou, Jiangsu 213013, China

### Statement of Quality Guarantee

According to REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023/amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, we hereby make the following statement:

- I. (a) The products listed in the Company's existing CE Certificate (NO: HD601436990001) continue to meet the requirements of Directive 93/42/EEC (MDD).
  - (b) As of May 26, 2024, there will not be a significant change in the design and intended use of the products listed in the Company's CE Certificate;
  - (c) The devices listed in the Certificate will not pose an unacceptable risk to the health or safety of patients, users, or others, or to other aspects of protecting public health.
- II. In view of the reasons in (a), (b) and (c) above, the products listed in the Company's Certificate (No.: HD601436990001) (see Annex 1) will remain in effect from June 04, 2023 to May 26, 2024.
- III. Besides the reasons in (a), (b) and (c) above, we have established a quality management system in accordance with the requirements of MDR (Regulation (EU) 2017/745) Article 10 (9), which covers the products listed in the Certificate; and we submitted a formal application for the conformity assessment in accordance with MDR in respect of these devices to the notified body in April 2022, also a written agreement for the conformity assessment was signed with the notified body. Relevant assessment work is in progress. The list of products is given in Annex 2. Therefore, the validity of these products' CE Certificate in Annex 2 will be extended to December 31, 2028.

Jiangsu Brightness Medical Devices Co., Ltd.

HATT



Jiangsu Brightness Medical Devices Company Limited
Address: The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road, Zhonglou Economic Development Area, Changzhou, Jiangsu 213013, China

April 17, 2023

# Annex 1 List of products, CE certificate valid until May 26, 2024

S/N	Product	Remarks
1.	Disposable Endoscopic Ligating Loops	
2.	Disposable Circular Staplers	
3.	Disposable Hemorrhoids Staplers	
4.	Disposable Linear Staplers and Reloads	
5.	Disposable Linear Cutter Staplers and Reloads	
6.	Skin Staplers and Removers	
7.	Disposable Curved Staplers	
8.	Disposable Endoscopic Dissectors	
9.	Disposable Endocutter & Disposable Endocutter Reload	
10.	Disposable Endoscopic Retrieval Bag	
11.	Disposable Clip Appliers	
12.	Disposable Trocars	
13.	Disposable Suction and Irrigation Tubes	
14.	Disposable Veress Needles	
15.	Bare-metal colonic stent	
16.	Bare-metal oesophageal stent	
17.	Bare-metal ureteral stent	
8.	Duodental stent	
9.	Bare-metal biliary stent	
0.	Bare-metal bronchial stent	





Jiangsu Brightness Medical Devices Company Limited
Address: The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road, Zhonglou Economic Development Area, Changzhou, Jiangsu 213013, China

# Annex 2 List of products, CE certificate valid until December 31, 2028

S/N	Product	Remarks
1.	Disposable Circular Staplers	
2.	Disposable Hemorrhoids Staplers	
3.	Disposable Linear Staplers and Reloads	
4.	Disposable Linear Cutter Staplers and Reloads	
5.	Disposable Endocutter & Disposable Endocutter Reload	
6.	Disposable Clip Appliers	
7.	Disposable Trocars	



**Document Title:** 

EC Declaration of Conformity

(Disposable Circular Staplers)

Revision:

A/0

Date:

12th, May., 2020

## **EC** Declaration of Conformity

(Disposable Circular Staplers)

Prepared by: Sherry a Lu

Checked by: 王泉顺

Approved by: Levin Jam

Manufacturer's name:

Jiangsu Brightness Medical Devices Co., Ltd.

Manufacturer's address:

The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road, Zhonglou Economic Development Area, Changzhou, Jiangsu

213013, China

EU Authorized Representative: Address:

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

**Disposable Circular Staplers** 

Model: As attached

GMDN-Code: 59875

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

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

C € 0197

The product has been designed and manufactured under a quality management system according to Annex II.3 of Directive 93/42/EEC.

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

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany

Certificate No.: HD 60143699 0001

Issue Date: 2020.04.26 Expiry Date: 2023.06.04

Following the procedure relating to the EC Declaration of Conformity set out in Annex II.3 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 -- Jiangsu

Brightness Medical Devices Co., Ltd.

(3. 2020-5-12

Legally binding signature, Function

Page 1 / 2

Annex: Product List of Disposable Circular Staplers

#### Medical device:

Product name: Disposable Circular Staplers

#### **Product List**:

Table 1 the specification of product

Catalogue No.	Specification
1	DH14
2	DH17
3	DH19
4	DH21
5	DH24
6	DH26
7	DH29
8	DH32
9	DH34
10	DHT21
11	DHT24
12	DHT26
13	DHT29
14	DHT32
15	DHT34

**Document Title:** 

EC Declaration of Conformity

(Disposable Endocutters & Disposable Endocutter Reloads)

Revision:

A/0

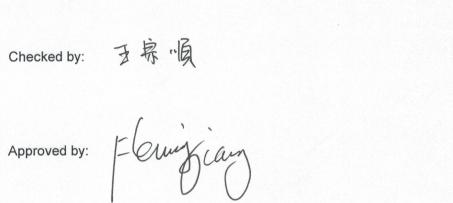
Date:

12th, May., 2020

### EC Declaration of Conformity

(Disposable Endocutters & Disposable Endocutter Reloads)

Prepared by: P本地度



Manufacturer's name:

Jiangsu Brightness Medical Devices Co., Ltd.

Manufacturer's address:

The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road, Zhonglou Economic Development Area, Changzhou, Jiangsu

213013, China

**EU Authorized Representative:** 

Lepu Medical (Europe) Cooperatief U.A.

Address:

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

#### Disposable Endocutters & Disposable Endocutter Reloads

Model: As attached

GMDN-Code: 59871

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

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

C € 0197

The product has been designed and manufactured under a quality management system according to Annex II.3 of Directive 93/42/EEC.

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

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany

Certificate No.: HD 60143699 0001

Issue Date: 2020.04.26 Expiry Date: 2023.06.04

Following the procedure relating to the EC Declaration of Conformity set out in Annex II.3 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 -- Jiangsu Brightness Medical Devices Co., Ltd.

(2, 2) 5/13 Place date

egally binding signature, Function

Page 1/3

Annex: Product List of Disposable Endocutters & Disposable Endocutter Reloads

#### Medical device:

Product name: Disposable Endocutters & Disposable Endocutter Reloads

### Product List:

Table 1 the specification of product

	Specification		
	Stapler models: JQ-A(B/L)	Stapler models: JQIIA(B/L)	Stapler models: BLEBS45, BLEBS60, BLEBM45,
		, ,	BLEBM60, BLEBL45, BLEBL60,
Outstand Na			BLEPS45, BLEPS60, BLEPM45,
Catalogue No.			BLEPM60, BLEPL45, BLEPL60,
			BLCBS45, BLCBS60, BLCBM45,
			BLCBM60, BLCBL45, BLCBL60,
			BLCPS45, BLCPS60, BLCPM45,
			BLCPM60, BLCPL45, BLCPL60
	Reload models:	Reload models:	Reload models:
1	JQZ-30-2.0	JJIIZ301	BLRSA45
2	JQZ-30-2.5	JJIIZ302	BLRSW45
3	JQZ-30-3.5	JJIIZ303	BLRSB45
4	JQZ-30-4.0	JJIIZ451	BLRSY45
5	JQZ-30-4.8	JJIIZ452	BLRSG45
6	JQZ-45-2.0	JJIIZ453	BLRSH45
7	JQZ-45-2.5	JJIIZ601	BLRSA60
8	JQZ-45-3.5	JJIIZ602	BLRSW60
9	JQZ-45-4.0	JJIIZ603	BLRSB60
10	JQZ-45-4.8	JJIID301	BLRSY60
11	JQZ-60-2.0	JJIID302	BLRSG60
12	JQZ-60-2.5	JJIID303	BLRSH60
13	JQZ-60-3.5	JJIID451	BLRPA45
14	JQZ-60-4.0	JJIID452	BLRPW45
15	JQZ-60-4.8	JJIID453	BLRPB45
16	JQD-30-2.0	JJIID601	BLRPY45
17	JQD-30-2.5	JJIID602	BLRPG45
18	JQD-30-3.5	JJIID603	BLRPH45
19	JQD-30-4.0		BLRPA60

Catalogue No.		Specification
20	JQD-30-4.8	BLRPW60
21	JQD-45-2.0	BLRPB60
22	JQD-45-2.5	BLRPY60
23	JQD-45-3.5	BLRPG60
24	JQD-45-4.0	BLRPH60
25	JQD-45-4.8	BLRSL45
26	JQD-60-2.0	BLRSM45
27	JQD-60-2.5	BLRSL60
28	JQD-60-3.5	BLRSM60
29	JQD-60-4.0	BLRPL45
30	JQD-60-4.8	BLRPM45
31		BLRPL60
32		BLRPM60



Document Title:

EC Declaration of Conformity

(Disposable Linear Cutter Staplers and Reloads)

Revision:

A/0

Date:

12th, May., 2020

## **EC** Declaration of Conformity

(Disposable Linear Cutter Staplers and Reloads)

Prepared by: Shenxia Lu

Checked by: 文泉順

Approved by: Floring Jian



Manufacturer's name: Manufacturer's address: Jiangsu Brightness Medical Devices Co., Ltd.

The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road, Zhonglou Economic Development Area, Changzhou, Jiangsu

213013, China

**EU Authorized Representative:** Address:

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

Disposable Linear Cutter Staplers and Reloads

Model: As attached

GMDN-Code: 59870

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

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

C E 0197

The product has been designed and manufactured under a quality management system according to Annex II.3 of Directive 93/42/EEC.

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

> TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany

Certificate No.: HD 60143699 0001

Issue Date: 2020.04.26 Expiry Date: 2023.06.04

Following the procedure relating to the EC Declaration of Conformity set out in Annex II.3 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 -- Jiangsu Brightness Medical Devices Co., Ltd.

(2. 2.20- f-12)
Place, date

Annex: Product List of Disposable Linear Cutter Staplers and Reloads

### Medical device:

Product name: Disposable Linear Cutter Staplers and Reloads

#### **Product List**:

Table 1 the specification of product

Catalogue No.	Specification
1	GH55(75/100)2(3/4)
2	QAB60(80/100)2(3/4)
3	GK55(75/100)2(3/4)
4	QB60(80/100)2(3/4)



Document Title:

**EC** Declaration of Conformity

(Disposable Linear Staplers and Reloads)

Revision:

A/0

Date:

12th, May., 2020

# EC Declaration of Conformity

(Disposable Linear Staplers and Reloads)

Prepared by: Shengia Lu

Checked by: 日泉順

Approved by: Floring Jeans

Manufacturer's name:

Jiangsu Brightness Medical Devices Co., Ltd.

Manufacturer's address:

The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road, Zhonglou Economic Development Area, Changzhou, Jiangsu

213013, China

**EU Authorized Representative:** 

Lepu Medical (Europe) Cooperatief U.A.

Address:

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

Disposable Linear Staplers and Reloads

Model: As attached GMDN-Code: 59873

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

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

# C € 0197

The product has been designed and manufactured under a quality management system according to Annex II.3 of Directive 93/42/EEC.

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

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany

Certificate No.: HD 60143699 0001

Issue Date: 2020.04.26 Expiry Date: 2023.06.04

Following the procedure relating to the EC Declaration of Conformity set out in Annex II.3 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 -- Jiangsu Brightness Medical Devices Co., Ltd.

Q. Jojo-J-12

Page 1/2

Annex: Product List of Disposable Linear Staplers and Reloads

### Medical device:

Product name: Disposable Linear Staplers and Reloads

### Product List:

Table 1 the specification of product

Table 1 the specification of product		
Catalogue No.	Specification	
1	CKH303(4)	
2	CKH453(4)	
3	CKH603(4)	
4	CKH753(4)	
5	CKH903(4)	
6	SAF30(45/60/75/90)2(3/4)	
7	CH303(4)	
8	CH453(4)	
9	CH603(4)	
10	CH753(4)	
11	CH903(4)	
12	SF30(45/60/75/90)2(3/4)	
13	HAF30	
14	HAF45	
15	HAF60	
16	HAF75	
17	HAF90	