**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.

Digitally signed by Cojocaru Vera
Date: 2024.10.01 07:11:07 EEST
Reason: MoldSign Signature
Location: Moldova

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**



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



2184-5

**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 IIb)** | |
|---|---|
| **Device Name:**<br>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 Reference | Action |
|---|---|---|---|
| 0 | 23 August 2023 | 6129535CN02 | first issue |
| 1 | | | |
| 2 | | | |

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



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



2184-5

# 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

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

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

**Attachment to Certificate**
**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:

- 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

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2020-04-26

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.

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

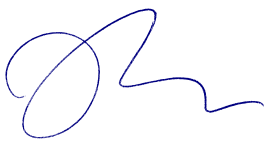
During the audit 3 nonconformities were raised. The Corrective Action Plan as provided by the legal manufacturer following the audit nonconformities are under reviewing by the DEKRA audit team.

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

**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

# 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.

**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 | |
| 18. | Duodental stent | |
| 19. | Bare-metal biliary stent | |
| 20. | 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<br>(Disposable Circular Staplers) |
| Revision: | A/0 |
| Date: | 12th, May., 2020 |

# EC Declaration of Conformity

## (Disposable Circular Staplers)

Prepared by: Shenxia Lu

Checked by: 王泉顺

Approved by: Haiying Jiang

| | |
|---|---|
| **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<br>Tel: +31-515-573399<br>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

CE 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.

CZ. 2020-5-12
*Place, date*

*Legally binding signature, Function*

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<br>(Disposable Endocutters & Disposable Endocutter Reloads) |
| Revision: | A/0 |
| Date: | 12th, May., 2020 |

# EC Declaration of Conformity

## (Disposable Endocutters & Disposable Endocutter Reloads)

Prepared by:

Checked by:

Approved by:

| | |
|---|---|
| **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<br>Tel: +31-515-573399<br>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

CE 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.

CZ, 2020/5/13
*Place, date*

Yiming Jiang / MR.
*Legally binding signature, Function*

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

| Catalogue No. | Specification | | |
|---|---|---|---|
| | Stapler models: JQ-A(B/L) | Stapler models: JQIIA(B/L) | Stapler models: BLEBS45, BLEBS60, BLEBM45, BLEBM60, BLEBL45, BLEBL60, BLEPS45, BLEPS60, BLEPM45, 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<br>(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: 支保顺

Approved by: Jiaqing Jiang

| | |
|---|---|
| **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<br>Tel: +31-515-573399<br>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

CE 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.

CZ. 2020-5-12
*Place, date*

Fleming Jiang / MR.
*Legally binding signature, Function*

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<br>(Disposable Linear Staplers and Reloads) |
| Revision: | A/0 |
| Date: | 12th, May., 2020 |

# EC Declaration of Conformity

## (Disposable Linear Staplers and Reloads)

Prepared by: Shengjia Lu

Checked by: 王康顺

Approved by: Fleming Jiang

| | |
|---|---|
| **Manufacturer's name:**<br>**Manufacturer's address:** | **Jiangsu Brightness Medical Devices Co., Ltd.**<br>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:**<br>**Address:** | **Lepu Medical (Europe) Cooperatief U.A.**<br>Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, the Netherlands<br>Tel: +31-515-573399<br>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

CE 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.

CZ. 2020-5-12
*Place, date*

Helmy Tian /MR.
*Legally binding signature, Function*

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

| 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 |