



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.

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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 | |





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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 | |

