Manufacturer Self-Declaration

Manufacturer's Name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturer's Address	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Manufacturer's SRN	CN-MF-000006950
EU Authorized Representative's Name	Shanghai International Holding Corp. GmbH (Europe)
EU Authorized Representative's Address	Eiffestrasse 80, 20537 Hamburg Germany
Product Name and Classification	Please refer to Attachment 1

We declare that our devices comply with the following aspects:

a) those devices continue to comply with Directive 93/42/EEC;

b) there are no significant changes in the design or intended purpose;

c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

d) we have put in place a quality management system in accordance with Article 10(9) of MDR 2017/745, before 26 May 2024;

e) we have lodged a formal application with BSI before 26 May 2024 in accordance with Section 4.3, first subparagraph, of Annex VII of MDR 2017/745 for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, we have signed a written agreement with BSI before 26 September 2024 in accordance with Section 4.3, second subparagraph, of Annex VII of MDR 2017/745.

f) we have undergone the first On-site audit under MDR by BSI Group The Netherlands B.V. in February 2020, and undergone the Surveillance Assessment under MDR in February 2023.

Signature: Becky Li

Name: Becky Li

Position: Person Responsible for Regulatory Compliance

Place and date of issue: Nanjing, 2023-07-19

Attachment 1 Product List

No.	Device Name	Classification	Certificate Number	Surveillance NB	Expiry Date
1	Single-Use Biopsy Forceps	Class IIa	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
2	Single Use Electrosurgical Knife	Class IIb - Non Implantable	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
3	Single Use Coagulation Forceps	Class IIb - Non Implantable	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
4	Endoscopic Ultrasound Aspiration Needle	Class IIa	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
5	Multiple Band Ligator Set	Class IIa	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
6	Sterile Disposable Hot Biopsy Forceps	Class IIb - Non Implantable	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028
7	Sterile Hot Snare	Class IIb - Non Implantable	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028
8	Sterile Cold Snare	Class IIa	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028
9	Sterile Repositionable Hemostasis Clipping Device	Class IIa	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028