EU MDR DECLARATION OF CONFORMITY

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, PRC
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
Authorized Representative's SRN	DE-AR-000000001
Product Name	Single-Use SD Biopsy Forceps
Product Trade Name	N/A
Basic UDI-DI	6802284DF6037896
Catalogue Number	BF16001, BF16002, BF16003, BF16004, BF16005, BF16006, BF10001, BF10002, BF10003, BF10004, BF10005, BF10006
GMDN Code	38711
EMDN Code	G03030101
Classification and Rule	Class IIa (According to Annex VIII, Rule 6 of MDR 2017/745)
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
Intended Purpose	The Single-Use SD Biopsy Forceps are designed to collect tissue samples in the pancreaticobiliary system endoscopically for histologic examination.

The Declaration of Conformity is issued under the sole responsibility of Micro-Tech (Nanjing) Co., Ltd. The device that is covered by the present declaration is in conformity with the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

General applicable Regulation:

REGULATION (EU) 2017/745 of medical device

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

The details, please see Attachment 1.

Notified Body (Name & Address):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identification Number:	CE 0344
Certificate Number:	6082015CE01
Certificate Issue Date:	2023-07-24
Certificate Expiry Date:	2027-09-01

Signature:

Becky Li

Name:

Position: Person Responsible for Regulatory Compliance

Place and date of issue:

Nanjing, PRC, 2023-11-07

Attachment 1

References to other union legislations, standards and common specification (if applicable) applied:

- EN ISO 13485:2016/A11:2021 Medical devices - Quality management systems – Requirements for regulatory purposes
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- EN ISO 20417:2021 Information supplied by the manufacturer with medical devices
- EN ISO 14971:2019/A11:2021 Medical devices – Application of risk management to medical devices
- ISO/TR 24971-2020 Medical devices – Guidance on the application of ISO 14971
- EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing
- EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-7:2008/AC:2009 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residua
- EN ISO 10993-10:2013 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- EN ISO 11135:2014/A1:2019 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11737-1:2018/A1:2021 Sterilization of health care products – Microbiological methods - Part 1: Determination of a population of microorganisms on products Sterilization of medical devices
- EN ISO 11737-2:2020 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1886/F1886M-16 Standard test method for determining integrity of seals for flexible packaging by visual inspection
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration
- ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- EN ISO 8536-4: 2020 Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)
- EN 62366-1:2015/AMD 1:2020 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 8600-1-2015 Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements
- EN ISO 14644-1:2015 Cleanroom and associated controlled environments – Part 1: Classification of air cleanliness
- EN 17141:2020 Cleanrooms and associated controlled environments – Biocontamination control
- MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI
- MDCG-2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG-2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance
- MDCG 2020-5 Clinical Evaluation – Equivalence A guide for manufacturers and notified

bodies

- MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
- IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation
- MEDDEV 2.7.1 (Rev. 4) Clinical evaluation: a guide for manufacturers and notified bodies
- MEDDEV 2.12.1 (Rev. 8) Guidelines on a medical devices vigilance system
- MEDDEV 2.12.2 (Rev. 2) Post market clinical follow-up studies a guide for manufacturers and notified bodies
- ISO/TR 20416 Medical devices – Post-market surveillance for manufacturers
- EC/1907/2006 REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)

Attachment 2 Catalogue Number

Number	REF	Number	REF
1	BF16001	7	BF10001
2	BF16002	8	BF10002
3	BF16003	9	BF10003
4	BF16004	10	BF10004
5	BF16005	11	BF10005
6	BF16006	12	BF10006

Revision History

Revision	Date	Description
A/0	2023-11-06	Initial