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, 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
EU Authorized Representative's SRN	DE-AR-000000001
Product Name	Single-Use Biopsy Forceps Disposable Biopsy Forceps
Product Trade Name	TruBite™ Single-Use Biopsy Forceps TechBite™ Single-Use Biopsy Forceps OptiBite* Disposable Biopsy Forceps
Basic UDI-DI	6902284BF387119Q
Catalogue Number	See attachment 2
GMDN code	38711
EMDN Code	G03080101: Gastrointestinal Endoscopy, Biopsy Forceps, Single-Use R07020101: Bronchoscopic Surgery Bioptic Forceps, Single-Use
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	These single-use biopsy forceps are used to collect living tissue samples of digestive tract and respiratory tract under the endoscopy.

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 detail harmonized standards 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: Becky Li
Person Responsible for Regulatory Compliance

Place and date of issue:

Nanjing, Jiangsu province, PRC, 2023-11-02

Attachment 1

• 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 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

• 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 residual

• 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/AMD 1:2019 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 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

• 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 F88/F88M-15 Standard test method for seal strength of flexible barrier materials

• 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

• 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 - Part 1 : General principles and methods

• EN ISO 80369-7:2017 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications

• 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 Guidance on Clinical Evaluation

•IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation

• MEDDEV 2.12-1 Rev8 2013+Additional Guidance on MEDDEV 2.12/1 Rev.8 July 2019 Guidelines on a medical devices vigilance system

• MEDDEV 2.7.1 Rev 4 Clinical evaluation: a guide for manufacturers and notified bodies

• ISO/TR 20416 Medical devices — Post-market surveillance for manufacturers

Attachment 2 Catalogue Number

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