Number: 6082015CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone
210032 Nanjing, Jiangsu Province
P. R. China
SRN ID.: CN-MF-000006950

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: 6082014CN

Additional certificate: 6126407TD01

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße, 80 20537 Hamburg, Germany

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.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **16 September 2022** Date: **1 August 2023** Expiry date**: 1 September 2027**

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

Number: 6082015CE01

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):

Active non-implantable imaging devices utilising non-ionizing radiation (MDA0202, class IIa)
Device name: - Single-Use Video Bronchoscopes - Digital Controllers - Single-Use Video Pancreaticobiliary Scopes - PB Digital Controllers

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN 1203, class IIa)
Device name: - Sterile Biliary Stone Retrieval Balloon Catheter (including Retrieval Balloon / short-wire compatible) - Biliary Plastic Stent Introducer (Biliary Plastic Stent Introducer, Biliary Plastic Stent Introducer/ short-wire compatible) - Dilation Balloon - Disposable Multistage Dilation Balloon Catheter - Non Vascular Sterile Hydro Slide Guidewire

Non-active non-implantable instruments (MDN 1208, class IIa)
Device name: - Extraction Basket (including Extraction Basket/short-wire compatible) - Nitinol Spiral Extraction Basket (including Nitinol Spiral Extraction Basket/short-wire compatible) - Injection Needle - Single-Use SD Biopsy Forceps - Single-Use Biopsy Forceps

First Issued: **16 September 2022** Date: **1 August 2023** Expiry date**: 1 September 2027**

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EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

SPHINCTEROTOMES (G030402, class IIb)	
Device name: - Sphincterotome / short-wire compatible - Sphincterotome	*Intended Purpose: The device is intended to be used with endoscope and guidewire for selective cannulation of the biliary ducts and monopolar cutting in sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi using high-frequency current. The device can also be used to inject contrast medium.*

Esophageal Prostheses-Other (P050199, class IIb implantable)	
Device name: - Esophageal Stent	*Intended Purpose: The Esophageal Stent implant is indicated for use in the palliative treatment of esophageal stricture caused by malignant neoplasms, cardia stricture, anastomotic stoma stricture, and the esophageal fistula occluding.*

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	16 September 2022	6082014CN02	First issue
1	20 April 2023	6082014CN04	Revised
2	18 July 2023	6082014CN06	Revised
3	24 July 2023	6082014CN07	Revised
4	1 August 2023	6082014CN08	Revised

First Issued: **16 September 2022** Date: **1 August 2023** Expiry date**: 1 September 2027**

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

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

NO	REF	NO	REF	NO	REF
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