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**

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

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