



MICRO-TECHTM
ENDOSCOPY

POLYPECTOMY SNARES

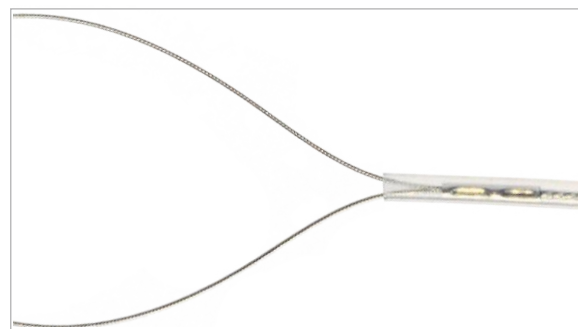
Speed and precision with every cut



Your **Trusted** Partner In Endoscopy!

KEY BENEFITS

- Very comfortable to use
- Reliable and safe
- Innovative power connection
- Ergonomic 3-ring handle
- Excellent cutting characteristics
- High strength of shape



SPECIFICATIONS

• Snares - Stiff

REF	Snare Shape	Snare Diameter (mm)	Sheath O.D. (mm)	Channel Size (mm)	Working Length (cm)	Packaging
PFS01-01023230	Oval	10	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-01523230	Oval	15	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-02023230	Oval	20	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-02423230	Oval	24	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-03023230	Oval	30	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-03623230	Oval	36	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-11523230	Hexagonal	15	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-12423230	Hexagonal	24	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-33023230	Combinational	30	2.3	$\geq \phi 2.8$	230	10/Box
PFS01-01023230	Oval	10	2.3	$\geq \phi 2.8$	230	10/Box

• Snares - Flexible

REF	Snare Shape	Snare Diameter (mm)	Sheath O.D. (mm)	Channel Size (mm)	Working Length (cm)	Packaging
PFS02-01023230	Oval	10	2.3	$\geq \phi 2.8$	230	10/Box
PFS02-01523230	Oval	15	2.3	$\geq \phi 2.8$	230	10/Box
PFS02-02023230	Oval	20	2.3	$\geq \phi 2.8$	230	10/Box
PFS02-02423230	Oval	24	2.3	$\geq \phi 2.8$	230	10/Box
PFS02-03023230	Oval	30	2.3	$\geq \phi 2.8$	230	10/Box

CAN'T FIND IT?

Additional items may be available. Contact us if you can't find what you need.



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+86-25-58646393

Micro-tech.com.cn/en/

Sales@micro-tech.com.cn



BIOPSY

FORCEPS AND BRUSHES



DISPOSABLE BIOPSY FORCEPS

WHERE TECHNOLOGY AND RELIABILITY MEET

The biopsy forceps are extraordinarily sharp, which guarantees safe and effortless removal of significant tissue specimens. The CamDesign of our TechBite™ requires only very gentle contact pressure for a very good biopsy. The shortened distal end goes easy on the working

channel, even in angled positions. This is always guaranteed by the fully-mechanized production system used to manufacture TechBite™. With its classic shear joints, the TruBite combines easy handling with reliable quality.

SPECIFIC CHARACTERISTICS

- Significant biopsies
- A design that goes easy on the working channel
- Short distal end: 9 mm (TechBite™), 11.5 mm (TruBite)
- Wide product range



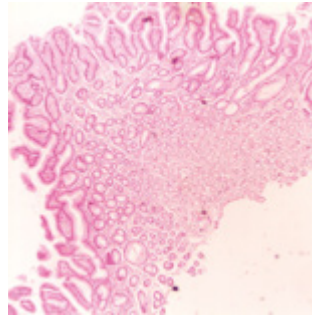
Cam-Design (Fig. TechBite™)



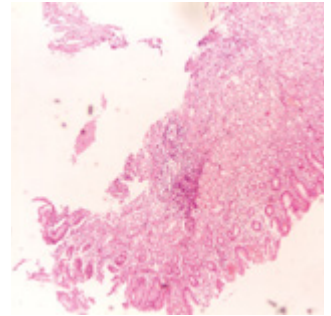
Scissors joint (Fig. TruBite)

CONVINCING IN PRACTICAL USE

All of our forceps are equipped with a polyethylene coating. The labels can be consulted at any time for information regarding the withdrawal of the biopsy forceps.



Biopsate removed with a toothed cutting edge



Biopsate removed with a smooth cutting edge



HANDLE AVAILABLE AS 1-RING VERSION

All forceps are equipped with the 1-ring handle. This allows you to use a one-hand grip method.

JAW SECTIONS FOR EVERY INTERVENTION

Whether for biopsies or for removal of small polyps – the disposable biopsy forceps are perfectly equipped for any task with different jaw sections: with a smooth or a toothed cutting edge, with or without a spike.



HIGH QUALITY COATING

The coating protects the working channel against scratching and provides a frictionless feed motion. The colored marking shows the removal of the forceps from the working channel in order to prevent damage to the mucous membrane. The forceps have been given different colors so they can be quickly allocated in accordance with working length:

Blue: 2300 mm or 2600 mm

Orange: 1800 mm

Yellow: Pediatric 1800 mm or 2600 mm

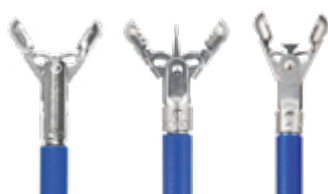
SELECTION OF MORE THAN 30 BIOPSY FORCEPS

The broad range includes forceps of various sizes, and with differing features. An extract from the portfolio can be found below, while page five (5) offers a complete overview.

TECHBITE™



Jaw Ø 2.3 mm,
180 cm length



Jaw Ø 2.3 mm,
230 cm length

TRUBITE



Jaw Ø 2.3 mm,
180 cm length



Jaw Ø 2.3 mm,
230 cm length

SPECIAL FORCEPS

TECHBITE™ PAEDIATRICS



Jaw Ø 1.8 mm,
180 cm length

MACRO



Jaw Ø 3.0 mm,
230 cm length

TRUBITE PAEDIATRICS



Jaw Ø 1.8 mm,
180 cm length

LARGE CAPACITY



Jaw Ø 2.4 mm,
180 cm length



Jaw Ø 2.4 mm,
180 cm length

SPECIFICATIONS

REF	Working channel Ø mm	Length mm	Opening width mm	Jaw Ø mm	Spike	T-Block	Covering	Jaw	Grip
TECHBITE™									
EBF33-11023180	2.8	1800	6.7	2.3	No	Yes	Orange	Smooth	1-ring
EBF33-11023230	2.8	2300	6.0	2.3	No	Yes	Blue	Smooth	1-ring
EBF33-11123180	2.8	1800	6.7	2.3	Yes	No	Orange	Smooth	1-ring
EBF33-11123230	2.8	2300	6.7	2.3	Yes	No	Blue	Smooth	1-ring
EBF43-11023180	2.8	1800	6.7	2.3	No	No	Orange	Serrated	1-ring
EBF43-11023230	2.8	2300	6.7	2.3	No	No	Blue	Serrated	1-ring
EBF43-11123180	2.8	1800	6.7	2.3	Yes	No	Orange	Serrated	1-ring
EBF43-11123230	2.8	2300	6.7	2.3	Yes	No	Blue	Serrated	1-ring
TRUBITE									
EBF53-11023180	2.8	1800	6.7	2.3	No	No	Orange	Smooth	1-ring
EBF53-11023230	2.8	2300	6.7	2.3	No	No	Blue	Smooth	1-ring
EBF53-11123180	2.8	1800	6.7	2.3	Yes	No	Orange	Smooth	1-ring
EBF53-11123230	2.8	2300	6.7	2.3	Yes	No	Blue	Smooth	1-ring
EBF63-11023180	2.8	1800	6.7	2.3	No	No	Orange	Serrated	1-ring
EBF63-11023230	2.8	2300	6.7	2.3	No	No	Blue	Serrated	1-ring
EBF63-11123180	2.8	1800	6.7	2.3	Yes	No	Orange	Serrated	1-ring
EBF63-11123230	2.8	2300	6.7	2.3	Yes	No	Blue	Serrated	1-ring
SPECIAL FORCEPS									
TECHBITE™ – PAEDIATRICS									
EBF33-11018180	2.0	1800	4.5	1.8	No	No	Yellow	Smooth	1-ring
EBF43-11018180	2.0	1800	4.5	1.8	No	No	Yellow	Serrated	1-ring
EBF43-11118180	2.0	1800	4.5	1.8	Yes	No	Yellow	Serrated	1-ring
TRUBITE – PAEDIATRICS									
EBF53-11018180	2.0	1800	4.5	1.8	No	No	Yellow	Smooth	1-ring
EBF53-11118180	2.0	1800	4.5	1.8	Yes	No	Yellow	Smooth	1-ring
EBF13-11018180	2.0	1800	4.5	1.8	No	No	Yellow	Serrated	1-ring
EBF13-11118180	2.0	1800	4.5	1.8	Yes	No	Yellow	Serrated	1-ring
TRUBITE – ENTEROSCOPY									
EBF03-11018260	2.0	2600	4.5	1.8	No	No	Yellow	Smooth	1-ring
EBF03-11023260	2.8	2600	6.7	2.3	No	No	Blue	Smooth	1-ring
TRUBITE – MACRO									
EBF03-01030230	3.2	2300	8.5	3.0	No	No	Blue	Smooth	1-ring
EBF03-01130230	3.2	2300	8.5	3.0	Yes	No	Blue	Smooth	1-ring
EBF13-01030230	3.2	2300	8.5	3.0	No	No	Blue	Serrated	1-ring
EBF13-01130230	3.2	2300	8.5	3.0	Yes	No	Blue	Serrated	1-ring
LARGE CAPACITY									
LCEBF63-10024180	2.8	1800	9.0	2.4	No	No	Orange	Serrated	1-ring
LCEBF63-10024230	2.8	2300	9.0	2.4	No	No	Blue	Serrated	1-ring
LCEBF63-10124180	2.8	1800	9.0	2.4	Yes	No	Orange	Serrated	1-ring
LCEBF63-10124230	2.8	2300	9.0	2.4	Yes	No	Blue	Serrated	1-ring

Packaging unit: 10 pieces



HOT BIOPSY FORCEPS

REMOVE BIOPSIES AND STOP BLEEDING

MICRO-TECH unites several therapeutic working steps with its practical 2-in-1 solution. On one hand, the hot biopsy forceps serve as conventional hot forceps, removing small colonic polyps precisely and safely in active mode while taking diagnostically conclusive tissue samples in non-active mode. On the other hand, they serve as an

urgent measure for stopping bleeding, since the smallest lesions can be closed again at any time via coagulation. In this respect, MICRO-TECH's hot biopsy forceps suitability for treating patients with increased risk of bleeding is unparalleled.

SPECIFIC CHARACTERISTICS

- Very comfortable to use
- High quality riveted scissors joints
- Puncture-proof PTFE insulation
- 3-ring handle with Olympus-HF-connection
- Excellent cutting properties



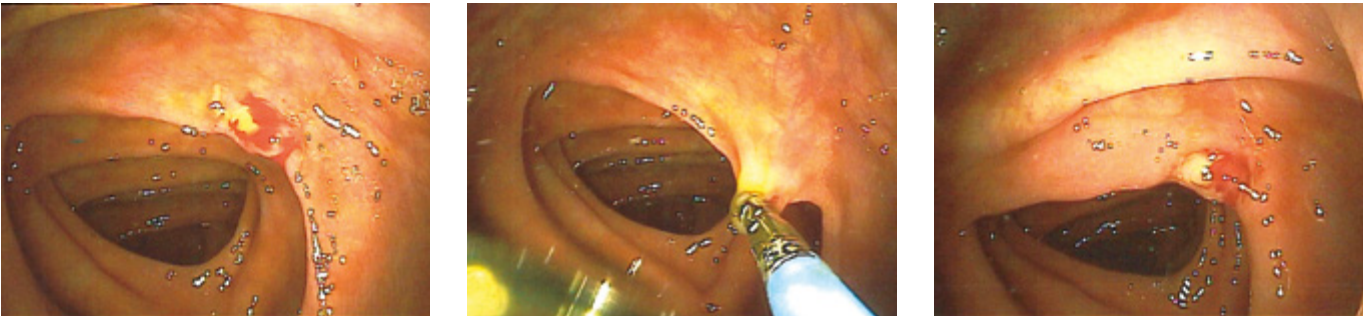
HF-connection



Scissors joint

SUCCESSFUL IN PRACTICAL USE

The hot biopsy forceps from MICRO-TECH are particularly suitable for use in patients with an increased risk of bleeding. If bleeding occurs during tissue sampling or polyp removal, this can be treated immediately and stopped via coagulation current.



Hot biopsy forceps in endoscopic use



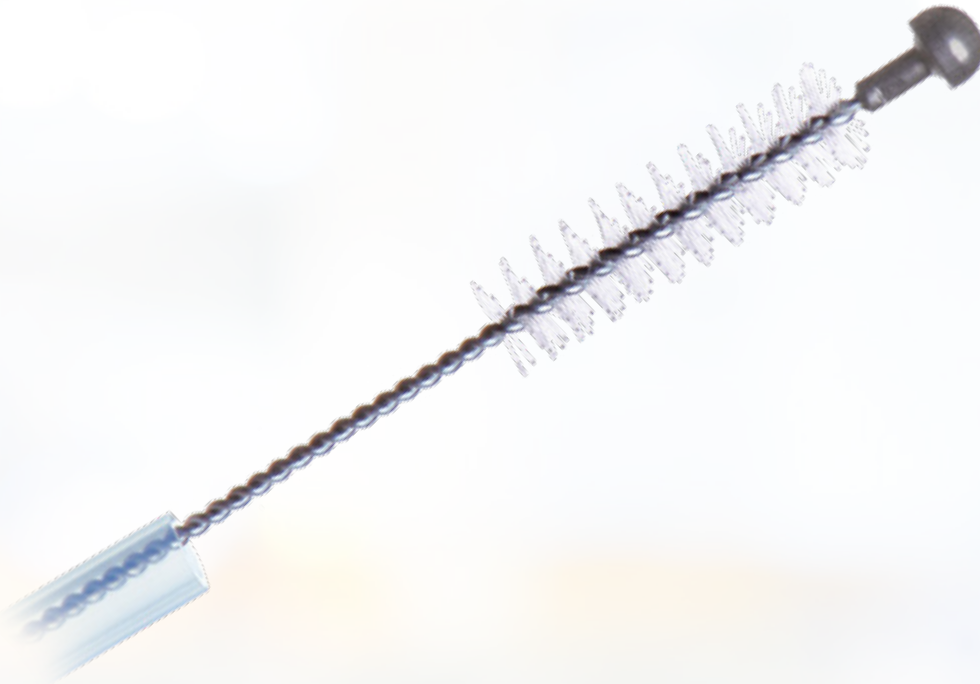
TARGET-ORIENTED USE OF POWER

The 3-ring handle is equipped with a universal HF-connection for safe and controlled power supply. The PTFE insulation of the metal coil is impact-resistant and prevents current conductive contact with the tissue.

SPECIFICATIONS

REF	Ø mm	Length mm	Spike	Insulated	Jaw
HOT-BIOPSY FORCEPS WITH COATING					
HBF05-11018120	1.8	1200	No	Yes	Standard
HBF05-11018180	1.8	1800	No	Yes	Standard
HBF05-11023180	2.3	1800	No	Yes	Standard
HBF05-11023230	2.3	2300	No	Yes	Standard

Packaging unit: 10 pieces



CYTOLOGY BRUSHES

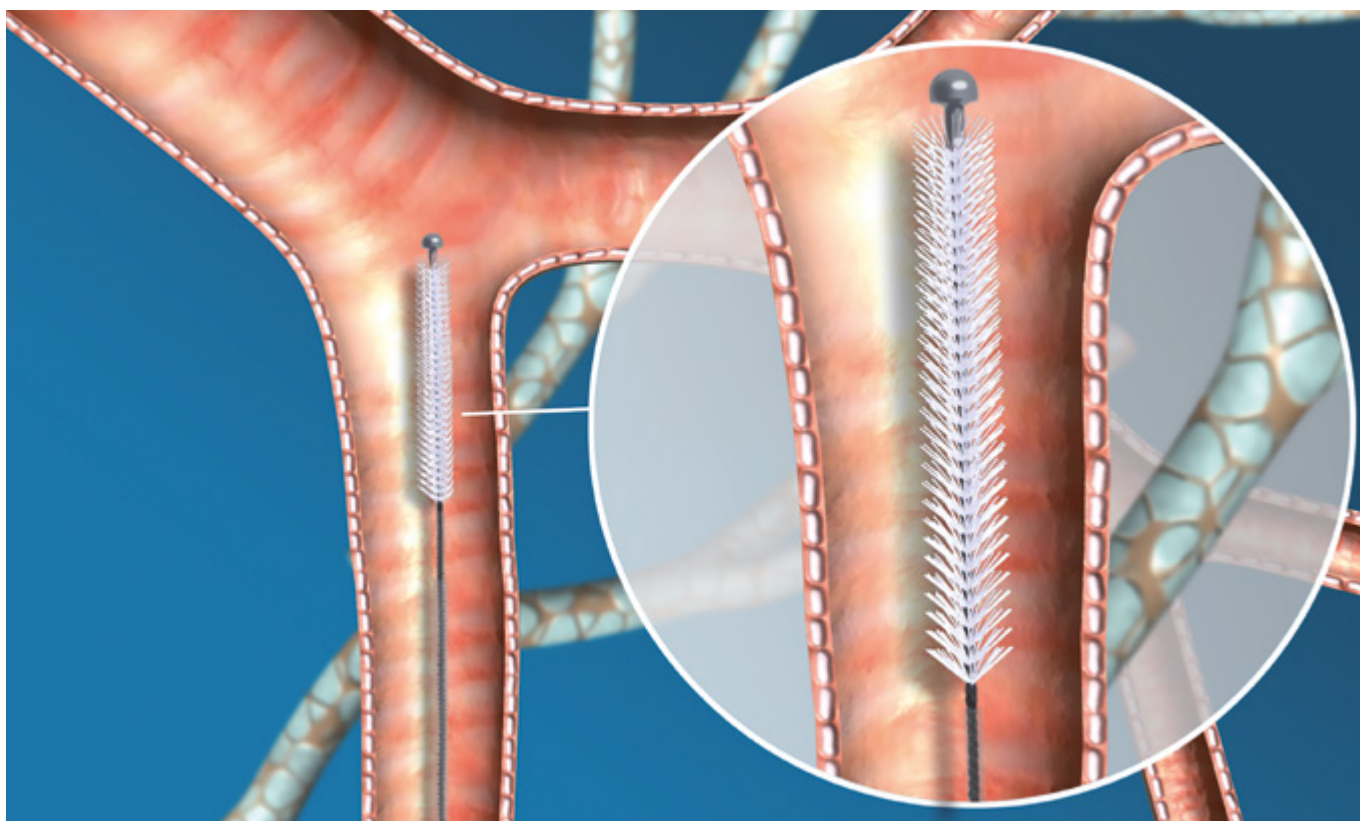
THE SOLUTION FOR EASY AND SAFE CYTOLOGIC SMEARS

One established method of acquiring cell specimens consists of taking cytologic smears with cytology brushes: MICRO-TECH makes cytologic smearing efficient and safe, owing to a series of cytology brushes which are especially adapted to clinical requirements. The MICRO-TECH cytology brush can be push forward easily to the desired

site through the endoscope. The thin bristles enable a tissue-sparing cytologic smear. The plastic tube and the distal ball for closure protect the tissue sample when the device is retracted. A potential contamination of the sample or even a loss of sample is thus excluded.

SPECIFIC CHARACTERISTICS

- Thin bristles for an optimal collection of cells
- Includes a plastic tube and a metal “ball shaped” head for tight closure
- For endoscopes with a minimum working channel diameter of 2.0 mm
- Sterile single packaging



SAFE AND CONTROLLED INTRODUCTION

By using MICRO-TECH cytology brushes, you can access lesions that are hard to reach, easily and safely. The ergonomically shaped 3-ring handle also gives the user a secure and comfortable grip. Every movement is conveyed to the brush head, directly and with precision.



Ergonomically handle

COMPREHENSIVE RANGE OF PRODUCTS

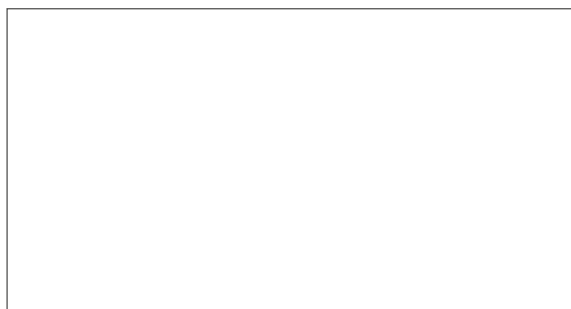
MICRO-TECH offers a great variety of cytology brush models which are suited for many application fields and comply with clinical specifications.

SPECIFICATIONS

REF	Brush Ø mm	Length mm	Catheter Ø mm
SINGLE-USE CYTOLOGY BRUSH			
CYB-24S-12C	2.4	1200	1.8
CYB-30S-12C	3.0	1200	1.8
CYB-30S-24C	3.0	2400	2.3
CYB-40S-12C	4.0	1200	1.8

Packaging unit: 20 pieces

NOTES



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

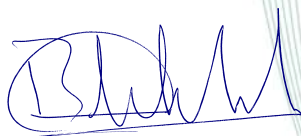
Authorized Representative:

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**

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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

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Expiry date: 1 September 2027

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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

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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:

Place and date of issue:

Becky Li
.....

NAME: Becky Li

Person Responsible for Regulatory
Compliance

Nanjing, Jiangsu province, P.R.C., 2023-11-02

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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



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- 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
1	BF01-11018120	2	BF01-11018160	3	BF01-11018180
4	BF01-11018230	5	BF01-11118120	6	BF01-11118160
7	BF01-11118180	8	BF01-11118230	9	BF03-11018120
10	BF03-11018160	11	BF03-11018180	12	BF03-11018230
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19	BF01-11023230	20	BF01-11123160	21	BF01-11123180
22	BF01-11123230	23	BF03-11023160	24	BF03-11023180
25	BF03-11023230	26	BF03-11123160	27	BF03-11123180
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37	BF11-11018180	38	BF11-11018230	39	BF11-11118120
40	BF11-11118160	41	BF11-11118180	42	BF11-11118230
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115	EBF01-01130120	116	EBF01-01130160	117	EBF01-01130180

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