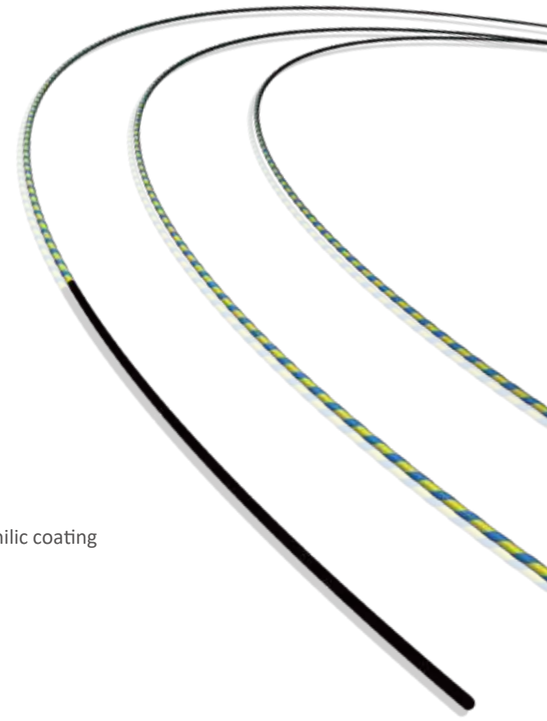
Notes and Future Product Updates

Non Vascular Sterile Hydro Slide Guidewire

The Non Vascular Sterile Hydro Slide Guidewire is mainly used with endoscope, imports or guides other equipments into a predetermined position of non vascular natural orifice such as biliary duct, pancreatic duct and so on, and plays a supporting or guiding role. All guidewires are manufactured out of Nitinol with good shape memory physical and mechanical properties. Owing to their hydrophilic tips, the wires safely find their way even into areas and stenosis which are hard to reach. This is supported by the wire's high rigidity and controllability.



Performance Characteristics:

- The core is made of super elastic alloy to prevent kinking.
- The atraumatic distal tip is made of soft polymeric material with hydrophilic coating to facilitate ease of cannulation.

Specifications:

Non Vascular Sterile Hydro Slide Guidewire

REF	Maximum O.D. (in)	Working Length (cm)	Tip Style	Packaging
MTN-BM-89/26-A	.035	260	Straight	2/Box
MTN-BM-89/26-A-J	.035	260	Angle	2/Box
MTN-BM-89/45-A	.035	450	Straight	2/Box
MTN-BM-89/45-A-J	.035	450	Angle	2/Box
MTN-BM-63/26-A	.025	260	Straight	2/Box
MTN-BM-63/26-A-J	.025	260	Angle	2/Box
MTN-BM-63/45-A	.025	450	Straight	2/Box
MTN-BM-63/45-A-J	.025	450	Angle	2/Box

YOUR TRUSTED PARTNER IN ENDOSCOPY

Injection Needle

Indications for endoscopy to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system; and the injection of saline to aid in Endoscopic Mucosal Resection (EMR), polypectomy procedures and to control non-variceal hemorrhage.

Performance Characteristics

- Lock to ensure that it would not accidentally extend during insertion to damage the scope and to have a stable needle penetration
- Needle release button design, gently press the button to return the needle fully into the sheath for protecting the endoscope from any damage
- Ergonomic handle design: complete needle insertion and withdrawal with one hand

Specifications

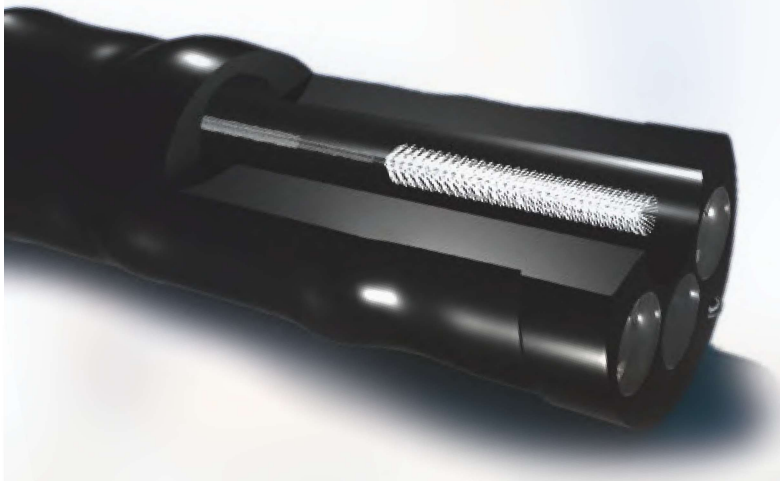
REF	Needle Gauge	Maximum Needle Extension Length (mm)	Sheath O.D. (Fr)	Working Length (mm)	Packaging
Injection Needle					
IN12-194231802	19G	4	7	1800	10/Box
IN12-194231802	19G	5	7	1800	10/Box
IN12-194231802	19G	6	7	1800	10/Box
IN12-194232302	19G	4	7	2300	10/Box
IN12-195232302	19G	5	7	2300	10/Box
IN12-196232302	19G	6	7	2300	10/Box
IN12-224232302	22G	4	7	2300	10/Box
IN12-225232302	22G	5	7	2300	10/Box
IN12-226232302	22G	6	7	2300	10/Box
IN12-254232302	25G	4	7	2300	10/Box
IN12-255232302	25G	5	7	2300	10/Box
IN12-256232302	25G	6	7	2300	10/Box
IN02-224231802	22G	4	7	1800	10/Box
IN02-224232002	22G	4	7	2000	10/Box
IN02-224232302	22G	4	7	2300	10/Box
IN02-225231802	22G	5	7	1800	10/Box
IN02-225232002	22G	5	7	2000	10/Box
IN02-225232302	22G	5	7	2300	10/Box
IN02-226231802	22G	6	7	1800	10/Box
IN02-226232002	22G	6	7	2000	10/Box
IN02-226232302	22G	6	7	2300	10/Box
IN02-254231802	25G	4	7	1800	10/Box
IN02-254232002	25G	4	7	2000	10/Box
IN02-254232302	25G	4	7	2300	10/Box
IN02-255231802	25G	5	7	1800	10/Box
IN02-255232002	25G	5	7	2000	10/Box
IN02-255232302	25G	5	7	2300	10/Box
IN02-256231802	25G	6	7	1800	10/Box
IN02-256232002	25G	6	7	2000	10/Box
IN02-256232302	25G	6	7	2300	10/Box

Specifications

REF	Required Working Channel (mm)	Scope O.D. (mm)	Bands / Ligating Unit	Band Type	Packaging
Multiple Band Ligator Set					
MBLS-7F-NL	2.8	9.4 -13.0	7pcs	Latex Free	1/Box
MBLS-6F-NL	2.8	9.4 -13.0	6pcs	Latex Free	1/Box
MBLS-4F-NL	2.8	9.4 -13.0	4pcs	Latex Free	1/Box
MBLS-7F	2.8	9.4 -13.0	7pcs	Latex	1/Box
MBLS-6F	2.8	9.4 -13.0	6pcs	Latex	1/Box
MBLS-4F	2.8	9.4 -13.0	4pcs	Latex	1/Box
MBLS-XL-7F-NL	2.8	11.0-14.0	7pcs	Latex Free	1/Box
MBLS-XL-6F-NL	2.8	11.0-14.0	6pcs	Latex Free	1/Box
MBLS-XL-4F-NL	2.8	11.0-14.0	4pcs	Latex Free	1/Box
MBLS-XL-7F	2.8	11.0-14.0	7pcs	Latex	1/Box
MBLS-XL-6F	2.8	11.0-14.0	6pcs	Latex	1/Box
MBLS-XL-4F	2.8	11.0-14.0	4pcs	Latex	1/Box

Disposable Cleaning Brush

The disposable cleaning brushes from MICRO-TECH ensure a perfectly cleaned endoscope, thus reducing the risk of cross-contamination to a minimum.



Performance Characteristics

- 2 brush heads for time-saving cleaning
- Protective beads on the brush heads
- Brushes made of resistant nylon
- Individually hygienically packed

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

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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

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