



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	Sphincterotome / short-wire compatible
Product Trade Name	N/A
Basic UDI-DI	6902284SS58039QB
Catalogue Number	See attachment 2
GMDN code	58039
EMDN Code	K020101
Classification and Rule	Class IIb (According to Annex VIII, Rule 9 of MDR 2017/745)
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
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.

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.

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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



Attachment 1

- EN ISO 13485:2016/11:2021 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 manufacture



Attachment 2 Catalogue Number

No.	REF	No.	REF	No.	REF	No.	REF
1	RDSP-0020-111	37	RDSP-0520-111	73	RDSP-0020-112	109	RDSP-0520-112
2	RDSP-0020-211	38	RDSP-0520-211	74	RDSP-0020-212	110	RDSP-0520-212
3	RDSP-0020-121	39	RDSP-0520-121	75	RDSP-0020-122	111	RDSP-0520-122
4	RDSP-0020-221	40	RDSP-0520-221	76	RDSP-0020-222	112	RDSP-0520-222
5	RDSP-0020-131	41	RDSP-0520-131	77	RDSP-0020-132	113	RDSP-0520-132
6	RDSP-0020-231	42	RDSP-0520-231	78	RDSP-0020-232	114	RDSP-0520-232
7	RDSP-0025-111	43	RDSP-0525-111	79	RDSP-0025-112	115	RDSP-0525-112
8	RDSP-0025-211	44	RDSP-0525-211	80	RDSP-0025-212	116	RDSP-0525-212
9	RDSP-0025-121	45	RDSP-0525-121	81	RDSP-0025-122	117	RDSP-0525-122
10	RDSP-0025-221	46	RDSP-0525-221	82	RDSP-0025-222	118	RDSP-0525-222
11	RDSP-0025-131	47	RDSP-0525-131	83	RDSP-0025-132	119	RDSP-0525-132
12	RDSP-0025-231	48	RDSP-0525-231	84	RDSP-0025-232	120	RDSP-0525-232
13	RDSP-0030-111	49	RDSP-0530-111	85	RDSP-0030-112	121	RDSP-0530-112
14	RDSP-0030-211	50	RDSP-0530-211	86	RDSP-0030-212	122	RDSP-0530-212
15	RDSP-0030-121	51	RDSP-0530-121	87	RDSP-0030-122	123	RDSP-0530-122
16	RDSP-0030-221	52	RDSP-0530-221	88	RDSP-0030-222	124	RDSP-0530-222
17	RDSP-0030-131	53	RDSP-0530-131	89	RDSP-0030-132	125	RDSP-0530-132
18	RDSP-0030-231	54	RDSP-0530-231	90	RDSP-0030-232	126	RDSP-0530-232
19	RDSP-0220-111	55	RDSP-1020-111	91	RDSP-0220-112	127	RDSP-1020-112
20	RDSP-0220-211	56	RDSP-1020-211	92	RDSP-0220-212	128	RDSP-1020-212
21	RDSP-0220-121	57	RDSP-1020-121	93	RDSP-0220-122	129	RDSP-1020-122
22	RDSP-0220-221	58	RDSP-1020-221	94	RDSP-0220-222	130	RDSP-1020-222

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No.	REF	No.	REF	No.	REF	No.	REF
23	RDSP-0220-131	59	RDSP-1020-131	95	RDSP-0220-132	131	RDSP-1020-132
24	RDSP-0220-231	60	RDSP-1020-231	96	RDSP-0220-232	132	RDSP-1020-232
25	RDSP-0225-111	61	RDSP-1025-111	97	RDSP-0225-112	133	RDSP-1025-112
26	RDSP-0225-211	62	RDSP-1025-211	98	RDSP-0225-212	134	RDSP-1025-212
27	RDSP-0225-121	63	RDSP-1025-121	99	RDSP-0225-122	135	RDSP-1025-122
28	RDSP-0225-221	64	RDSP-1025-221	100	RDSP-0225-222	136	RDSP-1025-222
29	RDSP-0225-131	65	RDSP-1025-131	101	RDSP-0225-132	137	RDSP-1025-132
30	RDSP-0225-231	66	RDSP-1025-231	102	RDSP-0225-232	138	RDSP-1025-232
31	RDSP-0230-111	67	RDSP-1030-111	103	RDSP-0230-112	139	RDSP-1030-112
32	RDSP-0230-211	68	RDSP-1030-211	104	RDSP-0230-212	140	RDSP-1030-212
33	RDSP-0230-121	69	RDSP-1030-121	105	RDSP-0230-122	141	RDSP-1030-122
34	RDSP-0230-221	70	RDSP-1030-221	106	RDSP-0230-222	142	RDSP-1030-222
35	RDSP-0230-131	71	RDSP-1030-131	107	RDSP-0230-132	143	RDSP-1030-132
36	RDSP-0230-231	72	RDSP-1030-231	108	RDSP-0230-232	144	RDSP-1030-232
37	RDSP-0520-111	37	RDSP-0520-111	73	RDSP-0020-112	109	RDSP-0520-112
38	RDSP-0520-211	38	RDSP-0520-211	74	RDSP-0020-212	110	RDSP-0520-212
39	RDSP-0520-121	39	RDSP-0520-121	75	RDSP-0020-122	111	RDSP-0520-122
40	RDSP-0520-221	40	RDSP-0520-221	76	RDSP-0020-222	112	RDSP-0520-222
41	RDSP-0520-131	41	RDSP-0520-131	77	RDSP-0020-132	113	RDSP-0520-132
42	RDSP-0520-231	42	RDSP-0520-231	78	RDSP-0020-232	114	RDSP-0520-232
43	RDSP-0525-111	43	RDSP-0525-111	79	RDSP-0025-112	115	RDSP-0525-112
44	RDSP-0525-211	44	RDSP-0525-211	80	RDSP-0025-212	116	RDSP-0525-212
45	RDSP-0525-121	45	RDSP-0525-121	81	RDSP-0025-122	117	RDSP-0525-122
46	RDSP-0525-221	46	RDSP-0525-221	82	RDSP-0025-222	118	RDSP-0525-222

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47	RDSP-0525-131	47	RDSP-0525-131	83	RDSP-0025-132	119	RDSP-0525-132
48	RDSP-0525-231	48	RDSP-0525-231	84	RDSP-0025-232	120	RDSP-0525-232
49	RDSP-0530-111	49	RDSP-0530-111	85	RDSP-0030-112	121	RDSP-0530-112
50	RDSP-0530-211	50	RDSP-0530-211	86	RDSP-0030-212	122	RDSP-0530-212
51	RDSP-0530-121	51	RDSP-0530-121	87	RDSP-0030-122	123	RDSP-0530-122
52	RDSP-0530-221	52	RDSP-0530-221	88	RDSP-0030-222	124	RDSP-0530-222
53	RDSP-0530-131	53	RDSP-0530-131	89	RDSP-0030-132	125	RDSP-0530-132
54	RDSP-0530-231	54	RDSP-0530-231	90	RDSP-0030-232	126	RDSP-0530-232
55	RDSP-1020-111	55	RDSP-1020-111	91	RDSP-0220-112	127	RDSP-1020-112
56	RDSP-1020-211	56	RDSP-1020-211	92	RDSP-0220-212	128	RDSP-1020-212
57	RDSP-1020-121	57	RDSP-1020-121	93	RDSP-0220-122	129	RDSP-1020-122
58	RDSP-1020-221	58	RDSP-1020-221	94	RDSP-0220-222	130	RDSP-1020-222
59	RDSP-1020-131	59	RDSP-1020-131	95	RDSP-0220-132	131	RDSP-1020-132
60	RDSP-1020-231	60	RDSP-1020-231	96	RDSP-0220-232	132	RDSP-1020-232
61	RDSP-1025-111	61	RDSP-1025-111	97	RDSP-0225-112	133	RDSP-1025-112
62	RDSP-1025-211	62	RDSP-1025-211	98	RDSP-0225-212	134	RDSP-1025-212
63	RDSP-1025-121	63	RDSP-1025-121	99	RDSP-0225-122	135	RDSP-1025-122
64	RDSP-1025-221	64	RDSP-1025-221	100	RDSP-0225-222	136	RDSP-1025-222
65	RDSP-1025-131	65	RDSP-1025-131	101	RDSP-0225-132	137	RDSP-1025-132
66	RDSP-1025-231	66	RDSP-1025-231	102	RDSP-0225-232	138	RDSP-1025-232
67	RDSP-1030-111	67	RDSP-1030-111	103	RDSP-0230-112	139	RDSP-1030-112
68	RDSP-1030-211	68	RDSP-1030-211	104	RDSP-0230-212	140	RDSP-1030-212
69	RDSP-1030-121	69	RDSP-1030-121	105	RDSP-0230-122	141	RDSP-1030-122
70	RDSP-1030-221	70	RDSP-1030-221	106	RDSP-0230-222	142	RDSP-1030-222

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72	RDSP-1030-231	72	RDSP-1030-231	108	RDSP-0230-232	144	RDSP-1030-232

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Revision History

Revision	Date	Description
A/0	2023-11-02	Initial