



Declaration of Conformity

Manufacturer	Micro-Tech (Nanjing) Co., Ltd.
Address	NO. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, P.R.China
European Representative	Shanghai International Holding Corp. GmbH (Europe)
Address	Eiffestrasse 80, 20537 Hamburg Germany
Product name	Sterile Sphincterotome
Model Number	Please see Attachment 2
UMDNS code	12239
Category	04 (Electro mechanical medical devices)
Classification	Class IIb (Annex IX, Rule 9 of MDD 93/42/EEC)
Conformity Assessment Route	Annex II (without II.4) of MDD 93/42/EEC

We herewith declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable Directives:

Medical Device Directive: Council Directive 93/42/EEC concerning medical devices

Standard Applied:

All applicable harmonized standards published in the Official Journal of the European Communities.

- ✧ EN ISO13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- ✧ EN ISO14971:2012 Medical devices - Application of risk management to medical devices
- Other standards see attachment
- ✧ EN1041:2008+A1:2013 Information supplied by the manufacturer with medical devices

The detail harmonized standards see Attachment 1.

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



Notified Body: SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium
Identification number: CE 1639
Certificate Number: CN19/41071
Expire date of the certificate: 2024-05-24
Place, Date of Certificate: Nanjing 2015-03-16

Signature: Frank Liu

Date: 2020-02-14

Name: Frank Liu

Position: Management Representative



Attachment 1

- ✧ Directive 93/42/EEC concerning medical devices.
- ✧ EN ISO13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- ✧ EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ✧ EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- ✧ ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing
- ✧ 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 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- ✧ EN ISO 11135:2014 Sterilization of health care products —Ethylene oxide —Requirements for development, validation and routine control of a sterilization process for medical devices
- ✧ EN ISO 11607-1:2017: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ✧ EN ISO 11607-2:2017: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- ✧ ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged-Products 150lb (68kg) or less)
- ✧ ASTM F1140/F1140M-13, Standard Test Methods For Internal Pressurization Failure Resistance Of Unrestrained Packages.
- ✧ ASTM F1886/F1886M: 2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ✧ EN1041:2008+A1: 2013 Information supplied by the manufacturer with medical devices
- ✧ SG5/N2R8:2007 Clinical Evaluation
- ✧ EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1:



Classification of air cleanliness

- ✧ EN ISO 11737-1:2018 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
- ✧ EN ISO 11737-2:2010 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ✧ ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ✧ EN 62366-1:2015 Medical devices – Application of usability engineering to medical devices
- ✧ MEDDEV 2.7.1 (Rev. 4) Clinical evaluation: a guide for manufacturers and notified bodies
- ✧ MEDDEV 2.12-1 (Rev. 8) Guidelines on a medical devices vigilance system
- ✧ MEDDEV 2.12/2 (Rev. 2) Post market clinical follow-up studies a guide for manufacturers and notified bodies
- ✧ EN ISO 14698-1:2003 Cleanrooms and associated controlled environments - Biocontamination control -Part 1 :General principles and methods
- ✧ ISO 8600-1: 2015 Optics and photonics —Medical endoscopes and endotherapy devices —Part 1: General requirements
- ✧ ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
- ✧ EN 60601-1:2013 Medical Electrical Equipment- Part 1: Medical electrical equipment – general requirements for the basic safety and essential performance
- ✧ EN 60601-2-2:2009 Medical electrical equipment Part 2-2: Particular requirements for the safety of high frequency surgical equipment
- ✧ EN 60601-2-18:2015 Medical electrical equipment Part 2-18:Particular requirements for the safety of endoscopic equipment



Attachment 2

Product List of Sterile Sphincterotome

No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
1	DSP-30020-111111	3	0	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
2	DSP-30020-111211	3	0	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
3	DSP-30025-111111	3	0	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
4	DSP-30025-111211	3	0	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
5	DSP-30030-111111	3	0	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
6	DSP-30030-111211	3	0	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
7	DSP-30220-111111	3	2	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
8	DSP-30220-111211	3	2	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
9	DSP-30225-111111	3	2	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
10	DSP-30225-111211	3	2	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
11	DSP-30230-111111	3	2	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
12	DSP-30230-111211	3	2	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
13	DSP-30520-111111	3	5	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
14	DSP-30520-111211	3	5	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
15	DSP-30525-111111	3	5	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
16	DSP-30525-111211	3	5	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
17	DSP-30530-111111	3	5	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
18	DSP-30530-111211	3	5	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
19	DSP-31020-111111	3	10	20	2.5	Cone	NO	NO	NO	Single	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
20	DSP-31020-111211	3	10	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
21	DSP-31025-111111	3	10	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
22	DSP-31025-111211	3	10	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
23	DSP-31030-111111	3	10	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
24	DSP-31030-111211	3	10	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
25	DSP-31520-111111	3	15	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
26	DSP-31520-111211	3	15	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
27	DSP-31525-111111	3	15	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
28	DSP-31525-111211	3	15	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
29	DSP-31530-111111	3	15	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
30	DSP-31530-111211	3	15	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
31	DSP-32020-111111	3	20	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
32	DSP-32020-111211	3	20	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
33	DSP-32025-111111	3	20	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
34	DSP-32025-111211	3	20	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
35	DSP-32030-111111	3	20	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
36	DSP-32030-111211	3	20	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
37	DSP-30020-111112	3	0	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
38	DSP-30020-111212	3	0	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
39	DSP-30025-111112	3	0	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
40	DSP-30025-111212	3	0	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
41	DSP-30030-111112	3	0	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
42	DSP-30030-111212	3	0	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
43	DSP-30220-111112	3	2	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
44	DSP-30220-111212	3	2	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
45	DSP-30225-111112	3	2	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
46	DSP-30225-111212	3	2	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
47	DSP-30230-111112	3	2	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
48	DSP-30230-111212	3	2	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
49	DSP-30520-111112	3	5	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
50	DSP-30520-111212	3	5	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
51	DSP-30525-111112	3	5	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
52	DSP-30525-111212	3	5	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
53	DSP-30530-111112	3	5	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
54	DSP-30530-111212	3	5	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
55	DSP-31020-111112	3	10	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
56	DSP-31020-111212	3	10	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
57	DSP-31025-111112	3	10	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
58	DSP-31025-111212	3	10	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
59	DSP-31030-111112	3	10	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
60	DSP-31030-111212	3	10	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
61	DSP-31520-111112	3	15	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
62	DSP-31520-111212	3	15	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
63	DSP-31525-111112	3	15	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
64	DSP-31525-111212	3	15	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
65	DSP-31530-111112	3	15	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
66	DSP-31530-111212	3	15	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
67	DSP-20020-111111	2	0	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
68	DSP-20020-111211	2	0	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
69	DSP-20025-111111	2	0	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
70	DSP-20025-111211	2	0	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
71	DSP-20030-111111	2	0	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
72	DSP-20030-111211	2	0	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
73	DSP-20220-111111	2	2	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
74	DSP-20220-111211	2	2	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
75	DSP-20225-111111	2	2	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
76	DSP-20225-111211	2	2	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
77	DSP-20230-111111	2	2	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
78	DSP-20230-111211	2	2	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
79	DSP-20520-111111	2	5	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
80	DSP-20520-111211	2	5	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
81	DSP-20525-111111	2	5	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
82	DSP-20525-111211	2	5	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
83	DSP-20530-111111	2	5	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
84	DSP-20530-111211	2	5	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
85	DSP-21020-111111	2	10	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
86	DSP-21020-111211	2	10	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
87	DSP-21025-111111	2	10	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
88	DSP-21025-111211	2	10	25	2.5	Cone	NO	YES	NO	Single	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
89	DSP-21030-111111	2	10	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
90	DSP-21030-111211	2	10	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
91	DSP-21520-111111	2	15	20	2.5	Cone	NO	NO	NO	Single	2000	2.8
92	DSP-21520-111211	2	15	20	2.5	Cone	NO	YES	NO	Single	2000	2.8
93	DSP-21525-111111	2	15	25	2.5	Cone	NO	NO	NO	Single	2000	2.8
94	DSP-21525-111211	2	15	25	2.5	Cone	NO	YES	NO	Single	2000	2.8
95	DSP-21530-111111	2	15	30	2.5	Cone	NO	NO	NO	Single	2000	2.8
96	DSP-21530-111211	2	15	30	2.5	Cone	NO	YES	NO	Single	2000	2.8
97	DSP-20020-111112	2	0	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
98	DSP-20020-111212	2	0	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
99	DSP-20025-111112	2	0	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
100	DSP-20025-111212	2	0	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
101	DSP-20030-111112	2	0	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
102	DSP-20030-111212	2	0	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
103	DSP-20220-111112	2	2	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
104	DSP-20220-111212	2	2	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
105	DSP-20225-111112	2	2	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
106	DSP-20225-111212	2	2	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
107	DSP-20230-111112	2	2	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
108	DSP-20230-111212	2	2	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
109	DSP-20520-111112	2	5	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
110	DSP-20520-111212	2	5	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
111	DSP-20525-111112	2	5	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
112	DSP-20525-111212	2	5	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
113	DSP-20530-111112	2	5	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
114	DSP-20530-111212	2	5	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
115	DSP-21020-111112	2	10	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
116	DSP-21020-111212	2	10	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
117	DSP-21025-111112	2	10	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
118	DSP-21025-111212	2	10	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
119	DSP-21030-111112	2	10	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
120	DSP-21030-111212	2	10	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
121	DSP-21520-111112	2	15	20	2.5	Cone	NO	NO	NO	Weave	2000	2.8
122	DSP-21520-111212	2	15	20	2.5	Cone	NO	YES	NO	Weave	2000	2.8
123	DSP-21525-111112	2	15	25	2.5	Cone	NO	NO	NO	Weave	2000	2.8
124	DSP-21525-111212	2	15	25	2.5	Cone	NO	YES	NO	Weave	2000	2.8
125	DSP-21530-111112	2	15	30	2.5	Cone	NO	NO	NO	Weave	2000	2.8
126	DSP-21530-111212	2	15	30	2.5	Cone	NO	YES	NO	Weave	2000	2.8
127	DSP-30505-121111	3	5	5	2.5	Needle Knife	NO	NO	NO	Single	2000	2.8
128	DSP-30505-121211	3	5	5	2.5	Needle Knife	NO	YES	NO	Single	2000	2.8
129	DSP-30507-121111	3	5	7	2.5	Needle Knife	NO	NO	NO	Single	2000	2.8
130	DSP-30507-121211	3	5	7	2.5	Needle Knife	NO	YES	NO	Single	2000	2.8
131	DSP-10505-121111	1	5	5	2.5	Needle Knife	NO	NO	NO	Single	2000	2.8
132	DSP-10505-121211	1	5	5	2.5	Needle Knife	NO	YES	NO	Single	2000	2.8
133	DSP-10507-121111	1	5	7	2.5	Needle Knife	NO	NO	NO	Single	2000	2.8
134	DSP-10507-121211	1	5	7	2.5	Needle Knife	NO	YES	NO	Single	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
135	DSP-30020-111121	3	0	20	2.5	Cone	NO	NO	YES	Single	2000	2.8
136	DSP-30020-111221	3	0	20	2.5	Cone	NO	YES	YES	Single	2000	2.8
137	DSP-30025-111121	3	0	25	2.5	Cone	NO	NO	YES	Single	2000	2.8
138	DSP-30025-111221	3	0	25	2.5	Cone	NO	YES	YES	Single	2000	2.8
139	DSP-30030-111121	3	0	30	2.5	Cone	NO	NO	YES	Single	2000	2.8
140	DSP-30030-111221	3	0	30	2.5	Cone	NO	YES	YES	Single	2000	2.8
141	DSP-30220-111121	3	2	20	2.5	Cone	NO	NO	YES	Single	2000	2.8
142	DSP-30220-111221	3	2	20	2.5	Cone	NO	YES	YES	Single	2000	2.8
143	DSP-30225-111121	3	2	25	2.5	Cone	NO	NO	YES	Single	2000	2.8
144	DSP-30225-111221	3	2	25	2.5	Cone	NO	YES	YES	Single	2000	2.8
145	DSP-30230-111121	3	2	30	2.5	Cone	NO	NO	YES	Single	2000	2.8
146	DSP-30230-111221	3	2	30	2.5	Cone	NO	YES	YES	Single	2000	2.8
147	DSP-30520-111121	3	5	20	2.5	Cone	NO	NO	YES	Single	2000	2.8
148	DSP-30520-111221	3	5	20	2.5	Cone	NO	YES	YES	Single	2000	2.8
149	DSP-30525-111121	3	5	25	2.5	Cone	NO	NO	YES	Single	2000	2.8
150	DSP-30525-111221	3	5	25	2.5	Cone	NO	YES	YES	Single	2000	2.8
151	DSP-30530-111121	3	5	30	2.5	Cone	NO	NO	YES	Single	2000	2.8
152	DSP-30530-111221	3	5	30	2.5	Cone	NO	YES	YES	Single	2000	2.8
153	DSP-30020-111122	3	0	20	2.5	Cone	NO	NO	YES	Weave	2000	2.8
154	DSP-30020-111222	3	0	20	2.5	Cone	NO	YES	YES	Weave	2000	2.8
155	DSP-30025-111122	3	0	25	2.5	Cone	NO	NO	YES	Weave	2000	2.8
156	DSP-30025-111222	3	0	25	2.5	Cone	NO	YES	YES	Weave	2000	2.8
157	DSP-30030-111122	3	0	30	2.5	Cone	NO	NO	YES	Weave	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
158	DSP-30030-111222	3	0	30	2.5	Cone	NO	YES	YES	Weave	2000	2.8
159	DSP-30220-111122	3	2	20	2.5	Cone	NO	NO	YES	Weave	2000	2.8
160	DSP-30220-111222	3	2	20	2.5	Cone	NO	YES	YES	Weave	2000	2.8
161	DSP-30225-111122	3	2	25	2.5	Cone	NO	NO	YES	Weave	2000	2.8
162	DSP-30225-111222	3	2	25	2.5	Cone	NO	YES	YES	Weave	2000	2.8
163	DSP-30230-111122	3	2	30	2.5	Cone	NO	NO	YES	Weave	2000	2.8
164	DSP-30230-111222	3	2	30	2.5	Cone	NO	YES	YES	Weave	2000	2.8
165	DSP-30520-111122	3	5	20	2.5	Cone	NO	NO	YES	Weave	2000	2.8
166	DSP-30520-111222	3	5	20	2.5	Cone	NO	YES	YES	Weave	2000	2.8
167	DSP-30525-111122	3	5	25	2.5	Cone	NO	NO	YES	Weave	2000	2.8
168	DSP-30525-111222	3	5	25	2.5	Cone	NO	YES	YES	Weave	2000	2.8
169	DSP-30530-111122	3	5	30	2.5	Cone	NO	NO	YES	Weave	2000	2.8
170	DSP-30530-111222	3	5	30	2.5	Cone	NO	YES	YES	Weave	2000	2.8
171	DSP-20020-111121	2	0	20	2.5	Cone	NO	NO	YES	Single	2000	2.8
172	DSP-20020-111221	2	0	20	2.5	Cone	NO	YES	YES	Single	2000	2.8
173	DSP-20025-111121	2	0	25	2.5	Cone	NO	NO	YES	Single	2000	2.8
174	DSP-20025-111221	2	0	25	2.5	Cone	NO	YES	YES	Single	2000	2.8
175	DSP-20030-111121	2	0	30	2.5	Cone	NO	NO	YES	Single	2000	2.8
176	DSP-20030-111221	2	0	30	2.5	Cone	NO	YES	YES	Single	2000	2.8
177	DSP-20220-111121	2	2	20	2.5	Cone	NO	NO	YES	Single	2000	2.8
178	DSP-20220-111221	2	2	20	2.5	Cone	NO	YES	YES	Single	2000	2.8
179	DSP-20225-111121	2	2	25	2.5	Cone	NO	NO	YES	Single	2000	2.8
180	DSP-20225-111221	2	2	25	2.5	Cone	NO	YES	YES	Single	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
181	DSP-20230-111121	2	2	30	2.5	Cone	NO	NO	YES	Single	2000	2.8
182	DSP-20230-111221	2	2	30	2.5	Cone	NO	YES	YES	Single	2000	2.8
183	DSP-20520-111121	2	5	20	2.5	Cone	NO	NO	YES	Single	2000	2.8
184	DSP-20520-111221	2	5	20	2.5	Cone	NO	YES	YES	Single	2000	2.8
185	DSP-20525-111121	2	5	25	2.5	Cone	NO	NO	YES	Single	2000	2.8
186	DSP-20525-111221	2	5	25	2.5	Cone	NO	YES	YES	Single	2000	2.8
187	DSP-20530-111121	2	5	30	2.5	Cone	NO	NO	YES	Single	2000	2.8
188	DSP-20530-111221	2	5	30	2.5	Cone	NO	YES	YES	Single	2000	2.8
189	DSP-20020-111122	2	0	20	2.5	Cone	NO	NO	YES	Weave	2000	2.8
190	DSP-20020-111222	2	0	20	2.5	Cone	NO	YES	YES	Weave	2000	2.8
191	DSP-20025-111122	2	0	25	2.5	Cone	NO	NO	YES	Weave	2000	2.8
192	DSP-20025-111222	2	0	25	2.5	Cone	NO	YES	YES	Weave	2000	2.8
193	DSP-20030-111122	2	0	30	2.5	Cone	NO	NO	YES	Weave	2000	2.8
194	DSP-20030-111222	2	0	30	2.5	Cone	NO	YES	YES	Weave	2000	2.8
195	DSP-20220-111122	2	2	20	2.5	Cone	NO	NO	YES	Weave	2000	2.8
196	DSP-20220-111222	2	2	20	2.5	Cone	NO	YES	YES	Weave	2000	2.8
197	DSP-20225-111122	2	2	25	2.5	Cone	NO	NO	YES	Weave	2000	2.8
198	DSP-20225-111222	2	2	25	2.5	Cone	NO	YES	YES	Weave	2000	2.8
199	DSP-20230-111122	2	2	30	2.5	Cone	NO	NO	YES	Weave	2000	2.8
200	DSP-20230-111222	2	2	30	2.5	Cone	NO	YES	YES	Weave	2000	2.8
201	DSP-20520-111122	2	5	20	2.5	Cone	NO	NO	YES	Weave	2000	2.8
202	DSP-20520-111222	2	5	20	2.5	Cone	NO	YES	YES	Weave	2000	2.8
203	DSP-20525-111122	2	5	25	2.5	Cone	NO	NO	YES	Weave	2000	2.8

Confidentiality: This document contains information that is confidential and proprietary property of Micro-Tech (Nanjing) CO., Ltd. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without prior written consent of Micro-Tech (Nanjing) CO., Ltd.



No.	REF	lumen	TIP length (mm)	cutting wire length (mm)	OD (mm)	TIP type	Rotation	half Insulation	preload guidewire	cutting wire type	working length (mm)	working channel (mm)
204	DSP-20525-111222	2	5	25	2.5	Cone	NO	YES	YES	Weave	2000	2.8
205	DSP-20530-111122	2	5	30	2.5	Cone	NO	NO	YES	Weave	2000	2.8
206	DSP-20530-111222	2	5	30	2.5	Cone	NO	YES	YES	Weave	2000	2.8
207	DSP-30505-121121	3	5	5	2.5	Needle Knife	NO	NO	YES	Single	2000	2.8
208	DSP-30505-121221	3	5	5	2.5	Needle Knife	NO	YES	YES	Single	2000	2.8
209	DSP-30507-121121	3	5	7	2.5	Needle Knife	NO	NO	YES	Single	2000	2.8
210	DSP-30507-121221	3	5	7	2.5	Needle Knife	NO	YES	YES	Single	2000	2.8