



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, People's Republic of China
European Shanghai International Holding Corp. GmbH (Europe)
Representative Eiffestrasse 80, 20537 Hamburg, Germany
Product name Biliary Drainage Catheter Set / short-wire compatible
REF Number Please refer to Attachment 1
UMDNS Code 10696
Classification IIa (According to MDD annex IX, rule 7)

Conformity Assessment Route Annex II (without II.4) of MDD 93/42/EEC

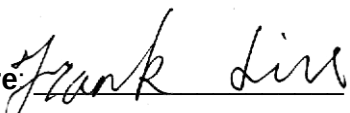
We herewith declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives. All supporting documentations are retained under the premises of the manufacturer. We're exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich,
Germany
Identification number: 0123
Certificate Number: G1 048850 0047
Expire date of the certificate: 2028-12-31
Place, Date of Certificate: 2019-05-17

Signature:  **Date:** 2023-07-20
Title: Management Representative



Attachment 1

Product List of Biliary Drainage Catheter Set / short-wire compatible Preloaded Biliary Drainage Catheter Set

NO.	REF	Biliary Drainage Catheter				Delivery System		Minimum working channel (mm)
		material	Shape	Catheter diameter (mm)	Effective length (mm)	Specification of assembled Biliary Drainage Catheter (mm)	Effective length (mm)	
1	RBPDS-3107-05/20	PE	straight	2.35 (7 Fr)	50	2.35 (7 Fr)	2050	3.2
2	RBPDS-3107-06/20	PE	straight	2.35 (7 Fr)	60	2.35 (7 Fr)	2050	3.2
3	RBPDS-3107-07/20	PE	straight	2.35 (7 Fr)	70	2.35 (7 Fr)	2050	3.2
4	RBPDS-3107-08/20	PE	straight	2.35 (7 Fr)	80	2.35 (7 Fr)	2050	3.2
5	RBPDS-3107-09/20	PE	straight	2.35 (7 Fr)	90	2.35 (7 Fr)	2050	3.2
6	RBPDS-3107-10/20	PE	straight	2.35 (7 Fr)	100	2.35 (7 Fr)	2050	3.2
7	RBPDS-3107-11/20	PE	straight	2.35 (7 Fr)	110	2.35 (7 Fr)	2050	3.2
8	RBPDS-3107-12/20	PE	straight	2.35 (7 Fr)	120	2.35 (7 Fr)	2050	3.2
9	RBPDS-3107-13/20	PE	straight	2.35 (7 Fr)	130	2.35 (7 Fr)	2050	3.2
10	RBPDS-3107-14/20	PE	straight	2.35 (7 Fr)	140	2.35 (7 Fr)	2050	3.2
11	RBPDS-3107-15/20	PE	straight	2.35 (7 Fr)	150	2.35 (7 Fr)	2050	3.2
12	RBPDS-3108-05/20	PE	straight	2.9 (8.5 Fr)	50	2.9 (8.5 Fr)	2050	3.2
13	RBPDS-3108-06/20	PE	straight	2.9 (8.5 Fr)	60	2.9 (8.5 Fr)	2050	3.2
14	RBPDS-3108-07/20	PE	straight	2.9 (8.5 Fr)	70	2.9 (8.5 Fr)	2050	3.2
15	RBPDS-3108-08/20	PE	straight	2.9 (8.5 Fr)	80	2.9 (8.5 Fr)	2050	3.2
16	RBPDS-3108-09/20	PE	straight	2.9 (8.5 Fr)	90	2.9 (8.5 Fr)	2050	3.2
17	RBPDS-3108-10/20	PE	straight	2.9 (8.5 Fr)	100	2.9 (8.5 Fr)	2050	3.2
18	RBPDS-3108-11/20	PE	straight	2.9 (8.5 Fr)	110	2.9 (8.5 Fr)	2050	3.2
19	RBPDS-3108-12/20	PE	straight	2.9 (8.5 Fr)	120	2.9 (8.5 Fr)	2050	3.2
20	RBPDS-3108-13/20	PE	straight	2.9 (8.5 Fr)	130	2.9 (8.5 Fr)	2050	3.2
21	RBPDS-3108-14/20	PE	straight	2.9 (8.5 Fr)	140	2.9 (8.5 Fr)	2050	3.2
22	RBPDS-3108-15/20	PE	straight	2.9 (8.5 Fr)	150	2.9 (8.5 Fr)	2050	3.2
23	RBPDS-3110-05/20	PE	straight	3.3 (10 Fr)	50	3.3 (10 Fr)	2050	4.2

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24	RBPDS-3110-06/20	PE	straight	3.3 (10 Fr)	60	3.3 (10 Fr)	2050	4.2
25	RBPDS-3110-07/20	PE	straight	3.3 (10 Fr)	70	3.3 (10 Fr)	2050	4.2
26	RBPDS-3110-08/20	PE	straight	3.3 (10 Fr)	80	3.3 (10 Fr)	2050	4.2
27	RBPDS-3110-09/20	PE	straight	3.3 (10 Fr)	90	3.3 (10 Fr)	2050	4.2
28	RBPDS-3110-10/20	PE	straight	3.3 (10 Fr)	100	3.3 (10 Fr)	2050	4.2
29	RBPDS-3110-11/20	PE	straight	3.3 (10 Fr)	110	3.3 (10 Fr)	2050	4.2
30	RBPDS-3110-12/20	PE	straight	3.3 (10 Fr)	120	3.3 (10 Fr)	2050	4.2
31	RBPDS-3110-13/20	PE	straight	3.3 (10 Fr)	130	3.3 (10 Fr)	2050	4.2
32	RBPDS-3110-14/20	PE	straight	3.3 (10 Fr)	140	3.3 (10 Fr)	2050	4.2
33	RBPDS-3110-15/20	PE	straight	3.3 (10 Fr)	150	3.3 (10 Fr)	2050	4.2
34	RBPDS-3207-05/20	PE	arcuate	2.35 (7 Fr)	50	2.35 (7 Fr)	2050	3.2
35	RBPDS-3207-06/20	PE	arcuate	2.35 (7 Fr)	60	2.35 (7 Fr)	2050	3.2
36	RBPDS-3207-07/20	PE	arcuate	2.35 (7 Fr)	70	2.35 (7 Fr)	2050	3.2
37	RBPDS-3207-08/20	PE	arcuate	2.35 (7 Fr)	80	2.35 (7 Fr)	2050	3.2
38	RBPDS-3207-09/20	PE	arcuate	2.35 (7 Fr)	90	2.35 (7 Fr)	2050	3.2
39	RBPDS-3207-10/20	PE	arcuate	2.35 (7 Fr)	100	2.35 (7 Fr)	2050	3.2
40	RBPDS-3207-11/20	PE	arcuate	2.35 (7 Fr)	110	2.35 (7 Fr)	2050	3.2
41	RBPDS-3207-12/20	PE	arcuate	2.35 (7 Fr)	120	2.35 (7 Fr)	2050	3.2
42	RBPDS-3207-13/20	PE	arcuate	2.35 (7 Fr)	130	2.35 (7 Fr)	2050	3.2
43	RBPDS-3207-14/20	PE	arcuate	2.35 (7 Fr)	140	2.35 (7 Fr)	2050	3.2
44	RBPDS-3207-15/20	PE	arcuate	2.35 (7 Fr)	150	2.35 (7 Fr)	2050	3.2
45	RBPDS-3208-05/20	PE	arcuate	2.9 (8.5 Fr)	50	2.9 (8.5 Fr)	2050	3.2
46	RBPDS-3208-06/20	PE	arcuate	2.9 (8.5 Fr)	60	2.9 (8.5 Fr)	2050	3.2
47	RBPDS-3208-07/20	PE	arcuate	2.9 (8.5 Fr)	70	2.9 (8.5 Fr)	2050	3.2
48	RBPDS-3208-08/20	PE	arcuate	2.9 (8.5 Fr)	80	2.9 (8.5 Fr)	2050	3.2
49	RBPDS-3208-09/20	PE	arcuate	2.9 (8.5 Fr)	90	2.9 (8.5 Fr)	2050	3.2
50	RBPDS-3208-10/20	PE	arcuate	2.9 (8.5 Fr)	100	2.9 (8.5 Fr)	2050	3.2
51	RBPDS-3208-11/20	PE	arcuate	2.9 (8.5 Fr)	110	2.9 (8.5 Fr)	2050	3.2
52	RBPDS-3208-12/20	PE	arcuate	2.9 (8.5 Fr)	120	2.9 (8.5 Fr)	2050	3.2
53	RBPDS-3208-13/20	PE	arcuate	2.9 (8.5 Fr)	130	2.9 (8.5 Fr)	2050	3.2
54	RBPDS-3208-14/20	PE	arcuate	2.9 (8.5 Fr)	140	2.9 (8.5 Fr)	2050	3.2

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55	RBPDS-3208-15/20	PE	arcuate	2.9 (8.5 Fr)	150	2.9 (8.5 Fr)	2050	3.2
56	RBPDS-3210-05/20	PE	arcuate	3.3 (10 Fr)	50	3.3 (10 Fr)	2050	4.2
57	RBPDS-3210-06/20	PE	arcuate	3.3 (10 Fr)	60	3.3 (10 Fr)	2050	4.2
58	RBPDS-3210-07/20	PE	arcuate	3.3 (10 Fr)	70	3.3 (10 Fr)	2050	4.2
59	RBPDS-3210-08/20	PE	arcuate	3.3 (10 Fr)	80	3.3 (10 Fr)	2050	4.2
60	RBPDS-3210-09/20	PE	arcuate	3.3 (10 Fr)	90	3.3 (10 Fr)	2050	4.2
61	RBPDS-3210-10/20	PE	arcuate	3.3 (10 Fr)	100	3.3 (10 Fr)	2050	4.2
62	RBPDS-3210-11/20	PE	arcuate	3.3 (10 Fr)	110	3.3 (10 Fr)	2050	4.2
63	RBPDS-3210-12/20	PE	arcuate	3.3 (10 Fr)	120	3.3 (10 Fr)	2050	4.2
64	RBPDS-3210-13/20	PE	arcuate	3.3 (10 Fr)	130	3.3 (10 Fr)	2050	4.2
65	RBPDS-3210-14/20	PE	arcuate	3.3 (10 Fr)	140	3.3 (10 Fr)	2050	4.2
66	RBPDS-3210-15/20	PE	arcuate	3.3 (10 Fr)	150	3.3 (10 Fr)	2050	4.2
67	RBPDS-3307-05/20	PE	side bend	2.35 (7 Fr)	50	2.35 (7 Fr)	2050	3.2
68	RBPDS-3307-06/20	PE	side bend	2.35 (7 Fr)	60	2.35 (7 Fr)	2050	3.2
69	RBPDS-3307-07/20	PE	side bend	2.35 (7 Fr)	70	2.35 (7 Fr)	2050	3.2
70	RBPDS-3307-08/20	PE	side bend	2.35 (7 Fr)	80	2.35 (7 Fr)	2050	3.2
71	RBPDS-3307-09/20	PE	side bend	2.35 (7 Fr)	90	2.35 (7 Fr)	2050	3.2
72	RBPDS-3307-10/20	PE	side bend	2.35 (7 Fr)	100	2.35 (7 Fr)	2050	3.2
73	RBPDS-3307-11/20	PE	side bend	2.35 (7 Fr)	110	2.35 (7 Fr)	2050	3.2
74	RBPDS-3307-12/20	PE	side bend	2.35 (7 Fr)	120	2.35 (7 Fr)	2050	3.2
75	RBPDS-3307-13/20	PE	side bend	2.35 (7 Fr)	130	2.35 (7 Fr)	2050	3.2
76	RBPDS-3307-14/20	PE	side bend	2.35 (7 Fr)	140	2.35 (7 Fr)	2050	3.2
77	RBPDS-3307-15/20	PE	side bend	2.35 (7 Fr)	150	2.35 (7 Fr)	2050	3.2
78	RBPDS-3308-05/20	PE	side bend	2.9 (8.5 Fr)	50	2.9 (8.5 Fr)	2050	3.2
79	RBPDS-3308-06/20	PE	side bend	2.9 (8.5 Fr)	60	2.9 (8.5 Fr)	2050	3.2
80	RBPDS-3308-07/20	PE	side bend	2.9 (8.5 Fr)	70	2.9 (8.5 Fr)	2050	3.2
81	RBPDS-3308-08/20	PE	side bend	2.9 (8.5 Fr)	80	2.9 (8.5 Fr)	2050	3.2
82	RBPDS-3308-09/20	PE	side bend	2.9 (8.5 Fr)	90	2.9 (8.5 Fr)	2050	3.2
83	RBPDS-3308-10/20	PE	side bend	2.9 (8.5 Fr)	100	2.9 (8.5 Fr)	2050	3.2
84	RBPDS-3308-11/20	PE	side bend	2.9 (8.5 Fr)	110	2.9 (8.5 Fr)	2050	3.2
85	RBPDS-3308-12/20	PE	side bend	2.9 (8.5 Fr)	120	2.9 (8.5 Fr)	2050	3.2

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86	RBPDS-3308-13/20	PE	side bend	2.9 (8.5 Fr)	130	2.9 (8.5 Fr)	2050	3.2
87	RBPDS-3308-14/20	PE	side bend	2.9 (8.5 Fr)	140	2.9 (8.5 Fr)	2050	3.2
88	RBPDS-3308-15/20	PE	side bend	2.9 (8.5 Fr)	150	2.9 (8.5 Fr)	2050	3.2
89	RBPDS-3310-05/20	PE	side bend	3.3 (10 Fr)	50	3.3 (10 Fr)	2050	4.2
90	RBPDS-3310-06/20	PE	side bend	3.3 (10 Fr)	60	3.3 (10 Fr)	2050	4.2
91	RBPDS-3310-07/20	PE	side bend	3.3 (10 Fr)	70	3.3 (10 Fr)	2050	4.2
92	RBPDS-3310-08/20	PE	side bend	3.3 (10 Fr)	80	3.3 (10 Fr)	2050	4.2
93	RBPDS-3310-09/20	PE	side bend	3.3 (10 Fr)	90	3.3 (10 Fr)	2050	4.2
94	RBPDS-3310-10/20	PE	side bend	3.3 (10 Fr)	100	3.3 (10 Fr)	2050	4.2
95	RBPDS-3310-11/20	PE	side bend	3.3 (10 Fr)	110	3.3 (10 Fr)	2050	4.2
96	RBPDS-3310-12/20	PE	side bend	3.3 (10 Fr)	120	3.3 (10 Fr)	2050	4.2
97	RBPDS-3310-13/20	PE	side bend	3.3 (10 Fr)	130	3.3 (10 Fr)	2050	4.2
98	RBPDS-3310-14/20	PE	side bend	3.3 (10 Fr)	140	3.3 (10 Fr)	2050	4.2
99	RBPDS-3310-15/20	PE	side bend	3.3 (10 Fr)	150	3.3 (10 Fr)	2050	4.2
100	RBPDS-3407-05/20	PE	center bend	2.35 (7 Fr)	50	2.35 (7 Fr)	2050	3.2
101	RBPDS-3407-06/20	PE	center bend	2.35 (7 Fr)	60	2.35 (7 Fr)	2050	3.2
102	RBPDS-3407-07/20	PE	center bend	2.35 (7 Fr)	70	2.35 (7 Fr)	2050	3.2
103	RBPDS-3407-08/20	PE	center bend	2.35 (7 Fr)	80	2.35 (7 Fr)	2050	3.2
104	RBPDS-3407-09/20	PE	center bend	2.35 (7 Fr)	90	2.35 (7 Fr)	2050	3.2
105	RBPDS-3407-10/20	PE	center bend	2.35 (7 Fr)	100	2.35 (7 Fr)	2050	3.2
106	RBPDS-3407-11/20	PE	center bend	2.35 (7 Fr)	110	2.35 (7 Fr)	2050	3.2
107	RBPDS-3407-12/20	PE	center bend	2.35 (7 Fr)	120	2.35 (7 Fr)	2050	3.2
108	RBPDS-3407-13/20	PE	center bend	2.35 (7 Fr)	130	2.35 (7 Fr)	2050	3.2
109	RBPDS-3407-14/20	PE	center bend	2.35 (7 Fr)	140	2.35 (7 Fr)	2050	3.2
110	RBPDS-3407-15/20	PE	center bend	2.35 (7 Fr)	150	2.35 (7 Fr)	2050	3.2
111	RBPDS-3408-05/20	PE	center bend	2.9 (8.5 Fr)	50	2.9 (8.5 Fr)	2050	3.2
112	RBPDS-3408-06/20	PE	center bend	2.9 (8.5 Fr)	60	2.9 (8.5 Fr)	2050	3.2
113	RBPDS-3408-07/20	PE	center bend	2.9 (8.5 Fr)	70	2.9 (8.5 Fr)	2050	3.2
114	RBPDS-3408-08/20	PE	center bend	2.9 (8.5 Fr)	80	2.9 (8.5 Fr)	2050	3.2
115	RBPDS-3408-09/20	PE	center bend	2.9 (8.5 Fr)	90	2.9 (8.5 Fr)	2050	3.2
116	RBPDS-3408-10/20	PE	center bend	2.9 (8.5 Fr)	100	2.9 (8.5 Fr)	2050	3.2

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117	RBPDS-3408-11/20	PE	center bend	2.9 (8.5 Fr)	110	2.9 (8.5 Fr)	2050	3.2
118	RBPDS-3408-12/20	PE	center bend	2.9 (8.5 Fr)	120	2.9 (8.5 Fr)	2050	3.2
119	RBPDS-3408-13/20	PE	center bend	2.9 (8.5 Fr)	130	2.9 (8.5 Fr)	2050	3.2
120	RBPDS-3408-14/20	PE	center bend	2.9 (8.5 Fr)	140	2.9 (8.5 Fr)	2050	3.2
121	RBPDS-3408-15/20	PE	center bend	2.9 (8.5 Fr)	150	2.9 (8.5 Fr)	2050	3.2
122	RBPDS-3410-05/20	PE	center bend	3.3 (10 Fr)	50	3.3 (10 Fr)	2050	4.2
123	RBPDS-3410-06/20	PE	center bend	3.3 (10 Fr)	60	3.3 (10 Fr)	2050	4.2
124	RBPDS-3410-07/20	PE	center bend	3.3 (10 Fr)	70	3.3 (10 Fr)	2050	4.2
125	RBPDS-3410-08/20	PE	center bend	3.3 (10 Fr)	80	3.3 (10 Fr)	2050	4.2
126	RBPDS-3410-09/20	PE	center bend	3.3 (10 Fr)	90	3.3 (10 Fr)	2050	4.2
127	RBPDS-3410-10/20	PE	center bend	3.3 (10 Fr)	100	3.3 (10 Fr)	2050	4.2
128	RBPDS-3410-11/20	PE	center bend	3.3 (10 Fr)	110	3.3 (10 Fr)	2050	4.2
129	RBPDS-3410-12/20	PE	center bend	3.3 (10 Fr)	120	3.3 (10 Fr)	2050	4.2
130	RBPDS-3410-13/20	PE	center bend	3.3 (10 Fr)	130	3.3 (10 Fr)	2050	4.2
131	RBPDS-3410-14/20	PE	center bend	3.3 (10 Fr)	140	3.3 (10 Fr)	2050	4.2
132	RBPDS-3410-15/20	PE	center bend	3.3 (10 Fr)	150	3.3 (10 Fr)	2050	4.2

Delivery System

No.	REF	Specification of assembled Biliary Drainage Catheter	Working length of delivery system(mm)	Minimum working channel(mm)
1	RBPDI-07/20	2.35 (7 Fr)	2050	3.2mm
2	RBPDI-08/20	2.9 (8.5 Fr)		3.2mm
3	RBPDI-10/20	3.3 (10 Fr)		4.2mm

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