



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 Biliary Stone Retrieval Balloon Catheter
Model Number	Please see Attachment 2
UMDNS code	15629
Category	10 (Single use devices)
Classification	Class IIa (Annex IX, Rule 5 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.

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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 10993-10:2013 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
- ✧ EN ISO 1618:1997 Catheters other than intravascular catheters-Test methods for common properties.
- ✧ ISO 10555-4-2013 Intravascular catheters — Sterile and single-use catheters —Part 4: Balloon dilatation catheters
- ✧ ISO 10555-1-2013Intravascular catheters — Sterile and single-use catheters —Part 1:General requirements
- ✧ EN 1707:1997 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings.



Attachment 2

Product List of Sterile Biliary Stone Retrieval Balloon Catheter

No.	REF	Work diameter (mm)	Working Length (mm)	Injection port
1	SRB-T-9-18	9	1800±100	Above
2	SRB-T-9-20	9	2000±100	Above
3	SRB-T-9-23	9	2300±100	Above
4	SRB-T-12-18	12	1800±100	Above
5	SRB-T-12-20	12	2000±100	Above
6	SRB-T-12-23	12	2300±100	Above
7	SRB-T-15-18	15	1800±100	Above
8	SRB-T-15-20	15	2000±100	Above
9	SRB-T-15-23	15	2300±100	Above
10	SRB-T-18-18	18	1800±100	Above
11	SRB-T-18-20	18	2000±100	Above
12	SRB-T-18-23	18	2300±100	Above
13	SRB-T-21-18	21	1800±100	Above
14	SRB-T-21-20	21	2000±100	Above
15	SRB-T-21-23	21	2300±100	Above
16	SRB-T-9/12-18	9/12	1800±100	Above
17	SRB-T-9/12-20	9/12	2000±100	Above
18	SRB-T-9/12-23	9/12	2300±100	Above
19	SRB-T-12/15-18	12/15	1800±100	Above
20	SRB-T-12/15-20	12/15	2000±100	Above
21	SRB-T-12/15-23	12/15	2300±100	Above
22	SRB-T-15/18-18	15/18	1800±100	Above
23	SRB-T-15/18-20	15/18	2000±100	Above
24	SRB-T-15/18-23	15/18	2300±100	Above
25	SRB-T-18/21-18	18/21	1800±100	Above
26	SRB-T-18/21-20	18/21	2000±100	Above
27	SRB-T-18/21-23	18/21	2300±100	Above
28	SRB-T-9/12/15-18	9/12/15	1800±100	Above
29	SRB-T-9/12/15-20	9/12/15	2000±100	Above
30	SRB-T-9/12/15-23	9/12/15	2300±100	Above
31	SRB-T-12/15/18-18	12/15/18	1800±100	Above
32	SRB-T-12/15/18-20	12/15/18	2000±100	Above
33	SRB-T-12/15/18-23	12/15/18	2300±100	Above
34	SRB-T-15/18/21-18	15/18/21	1800±100	Above
35	SRB-T-15/18/21-20	15/18/21	2000±100	Above

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36	SRB-T-15/18/21-23	15/18/21	2300±100	Above
37	SRB-T-9-18-B	9	1800±100	Below
38	SRB-T-9-20-B	9	2000±100	Below
39	SRB-T-9-23-B	9	2300±100	Below
40	SRB-T-12-18-B	12	1800±100	Below
41	SRB-T-12-20-B	12	2000±100	Below
42	SRB-T-12-23-B	12	2300±100	Below
43	SRB-T-15-18-B	15	1800±100	Below
44	SRB-T-15-20-B	15	2000±100	Below
45	SRB-T-15-23-B	15	2300±100	Below
46	SRB-T-18-18-B	18	1800±100	Below
47	SRB-T-18-20-B	18	2000±100	Below
48	SRB-T-18-23-B	18	2300±100	Below
49	SRB-T-21-18-B	21	1800±100	Below
50	SRB-T-21-20-B	21	2000±100	Below
51	SRB-T-21-23-B	21	2300±100	Below
52	SRB-T-9/12-18-B	9/12	1800±100	Below
53	SRB-T-9/12-20-B	9/12	2000±100	Below
54	SRB-T-9/12-23-B	9/12	2300±100	Below
55	SRB-T-12/15-18-B	12/15	1800±100	Below
56	SRB-T-12/15-20-B	12/15	2000±100	Below
57	SRB-T-12/15-23-B	12/15	2300±100	Below
58	SRB-T-15/18-18-B	15/18	1800±100	Below
59	SRB-T-15/18-20-B	15/18	2000±100	Below
60	SRB-T-15/18-23-B	15/18	2300±100	Below
61	SRB-T-18/21-18-B	18/21	1800±100	Below
62	SRB-T-18/21-20-B	18/21	2000±100	Below
63	SRB-T-18/21-23-B	18/21	2300±100	Below
64	SRB-T-9/12/15-18-B	9/12/15	1800±100	Below
65	SRB-T-9/12/15-20-B	9/12/15	2000±100	Below
66	SRB-T-9/12/15-23-B	9/12/15	2300±100	Below
67	SRB-T-12/15/18-18-B	12/15/18	1800±100	Below
68	SRB-T-12/15/18-20-B	12/15/18	2000±100	Below
69	SRB-T-12/15/18-23-B	12/15/18	2300±100	Below
70	SRB-T-15/18/21-18-B	15/18/21	1800±100	Below
71	SRB-T-15/18/21-20-B	15/18/21	2000±100	Below
72	SRB-T-15/18/21-23-B	15/18/21	2300±100	Below

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