



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 Representative	Shanghai International Holding Corp. GmbH (Europe)
Address	Eiffestrasse 80, 20537 Hamburg Germany
Product name	Disposable Multistage Dilation Balloon Catheter
Model Number	See Attachment 2
UMDNS code	17745
Category	10 (Single use devices)
Classification	IIa (Annex IX, Rule 6 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
- 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, 2016-01-11

Signature: Frank Liu **Date** 2020-02-14

Name: Frank Liu

Position: Management Representative



Attachment 1

- ✧ Directive 93/42/EEC concerning medical devices amended by directive 2007/47/EC
- ✧ EN ISO13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- ✧ ENISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ✧ ENISO 14971:2012 Medical devices - Application of risk management to medical devices
- ✧ EN ISO 10993-1:2009+AC: 2010 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–16 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

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- ✧ 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
 - ✧ 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 10555-1-2013 Intravascular catheters — Sterile and single-use catheters —Part 1: General requirements
 - ✧ MEDDEV 2.7.1 (Rev. 4, 2016) Clinical evaluation: a guide for manufacturers and notified bodies
 - ✧ MEDDEV 2.12.1 (Rev. 8, 2013) Guidelines on a medical devices vigilance system
 - ✧ MEDDEV 2.12.2 (Rev. 2, 2012) Post market clinical follow-up studies a guide for manufacturers and notified bodies
 - ✧ EN ISO 14698-1:2014 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 (ISO 80369-7:2016)



Attachment 2

Product List of Disposable Multistage Dilation Balloon Catheter

No.	REF	Balloon OD : Φ(mm)	Balloon 3 stage dilation pressure: P1-P2-P3 (atm)	Balloon 3 stage dilation pressure: P1-P2-P3 (Kpa)	Balloon length: L2 (mm)	Catheter length: L1(mm)	Compatible Guidewire	Working Channel	Guide wire type
1	MBD-AM-BB-0	6-7-8	3-6-10	304-608-1013	55	2300	0.035inch (0.89mm)	≥2.8mm	NA
2	MBD-BM-BB-0	8-9-10	3-5.5-9	304-557-912	55	2300	0.035inch (0.89mm)	≥2.8mm	NA
3	MBD-CM-BB-0	10-11-12	3-5-8	304-507-811	55	2300	0.035inch (0.89mm)	≥2.8mm	NA
4	MBD-DM-BB-0	12-13.5-15	3-4.5-8	304-456-811	55	2300	0.035inch (0.89mm)	≥2.8mm	NA
5	MBD-EM-BB-0	15-16.5-18	3-4.5-7	304-456-709	55	2300	0.035inch (0.89mm)	≥2.8mm	NA
6	MBD-FM-BB-0	18-19-20	3-4.5-6	304-456-608	55	2300	0.035inch (0.89mm)	≥2.8mm	NA
7	MBD-AM-BA-0	6-7-8	3-6-10	304-608-1013	55	1800	0.035inch (0.89mm)	≥2.8mm	NA
8	MBD-BM-BA-0	8-9-10	3-5.5-9	304-557-912	55	1800	0.035inch (0.89mm)	≥2.8mm	NA
9	MBD-CM-BA-0	10-11-12	3-5-8	304-507-811	55	1800	0.035inch (0.89mm)	≥2.8mm	NA

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No.	REF	Balloon OD : Φ(mm)	Balloon 3 stage dilation pressure: P1-P2-P3 (atm)	Balloon 3 stage dilation pressure: P1-P2-P3 (Kpa)	Balloon length: L2 (mm)	Catheter length: L1(mm)	Compatible Guidewire	Working Channel	Guide wire type
10	MBD-DM-BA-0	12-13.5-15	3-4.5-8	304-456-811	55	1800	0.035inch (0.89mm)	≥2.8mm	NA
11	MBD-EM-BA-0	15-16.5-18	3-4.5-7	304-456-709	55	1800	0.035inch (0.89mm)	≥2.8mm	NA
12	MBD-FM-BA-0	18-19-20	3-4.5-6	304-456-608	55	1800	0.035inch (0.89mm)	≥2.8mm	NA
13	MBD-AL-BA-0	6-7-8	3-6-10	304-608-1013	80	1800	0.035inch (0.89mm)	≥2.8mm	NA
14	MBD-BL-BA-0	8-9-10	3-5.5-9	304-557-912	80	1800	0.035inch (0.89mm)	≥2.8mm	NA
15	MBD-CL-BA-0	10-11-12	3-5-8	304-507-811	80	1800	0.035inch (0.89mm)	≥2.8mm	NA
16	MBD-DL-BA-0	12-13.5-15	3-4.5-8	304-456-811	80	1800	0.035inch (0.89mm)	≥2.8mm	NA
17	MBD-EL-BA-0	15-16.5-18	3-4.5-7	304-456-709	80	1800	0.035inch (0.89mm)	≥2.8mm	NA
18	MBD-FL-BA-0	18-19-20	3-4.5-6	304-456-608	80	1800	0.035inch (0.89mm)	≥2.8mm	NA
19	MBD-AS-BB-0	6-7-8	3-6-10	304-608-1013	30	2300	0.035inch (0.89mm)	≥2.8mm	NA
20	MBD-BS-BB-0	8-9-10	3-5.5-9	304-557-912	30	2300	0.035inch (0.89mm)	≥2.8mm	NA

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No.	REF	Balloon OD : Φ(mm)	Balloon 3 stage dilation pressure: P1-P2-P3 (atm)	Balloon 3 stage dilation pressure: P1-P2-P3 (Kpa)	Balloon length: L2 (mm)	Catheter length: L1(mm)	Compatible Guidewire	Working Channel	Guide wire type
21	MBD-CS-BB-0	10-11-12	3-5-8	304-507-811	30	2300	0.035inch (0.89mm)	≥2.8mm	NA
22	MBD-DS-BB-0	12-13.5-15	3-4.5-8	304-456-811	30	2300	0.035inch (0.89mm)	≥2.8mm	NA
23	MBD-AS-BA-0	6-7-8	3-6-10	304-608-1013	30	1800	0.035inch (0.89mm)	≥2.8mm	NA
24	MBD-BS-BA-0	8-9-10	3-5.5-9	304-557-912	30	1800	0.035inch (0.89mm)	≥2.8mm	NA
25	MBD-CS-BA-0	10-11-12	3-5-8	304-507-811	30	1800	0.035inch (0.89mm)	≥2.8mm	NA
26	MBD-DS-BA-0	12-13.5-15	3-4.5-8	304-456-811	30	1800	0.035inch (0.89mm)	≥2.8mm	NA
27	MBD-AM-BB-1	6-7-8	3-6-10	304-608-1013	55	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
28	MBD-BM-BB-1	8-9-10	3-5.5-9	304-557-912	55	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
29	MBD-CM-BB-1	10-11-12	3-5-8	304-507-811	55	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
30	MBD-DM-BB-1	12-13.5-15	3-4.5-8	304-456-811	55	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
31	MBD-EM-BB-1	15-16.5-18	3-4.5-7	304-456-709	55	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire

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No.	REF	Balloon OD : Φ(mm)	Balloon 3 stage dilation pressure: P1-P2-P3 (atm)	Balloon 3 stage dilation pressure: P1-P2-P3 (Kpa)	Balloon length: L2 (mm)	Catheter length: L1(mm)	Compatible Guidewire	Working Channel	Guide wire type
32	MBD-FM-BB-1	18-19-20	3-4.5-6	304-456-608	55	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
33	MBD-AM-BA-1	6-7-8	3-6-10	304-608-1013	55	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
34	MBD-BM-BA-1	8-9-10	3-5.5-9	304-557-912	55	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
35	MBD-CM-BA-1	10-11-12	3-5-8	304-507-811	55	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
36	MBD-DM-BA-1	12-13.5-15	3-4.5-8	304-456-811	55	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
37	MBD-EM-BA-1	15-16.5-18	3-4.5-7	304-456-709	55	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
38	MBD-FM-BA-1	18-19-20	3-4.5-6	304-456-608	55	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
39	MBD-AL-BA-1	6-7-8	3-6-10	304-608-1013	80	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
40	MBD-BL-BA-1	8-9-10	3-5.5-9	304-557-912	80	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
41	MBD-CL-BA-1	10-11-12	3-5-8	304-507-811	80	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
42	MBD-DL-BA-1	12-13.5-15	3-4.5-8	304-456-811	80	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire

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43	MBD-EL-BA-1	15-16.5-18	3-4.5-7	304-456-709	80	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
44	MBD-FL-BA-1	18-19-20	3-4.5-6	304-456-608	80	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
45	MBD-AS-BB-1	6-7-8	3-6-10	304-608-1013	30	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
46	MBD-BS-BB-1	8-9-10	3-5.5-9	304-557-912	30	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
47	MBD-CS-BB-1	10-11-12	3-5-8	304-507-811	30	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
48	MBD-DS-BB-1	12-13.5-15	3-4.5-8	304-456-811	30	2300	0.035inch (0.89mm)	≥2.8mm	Supporting wire
49	MBD-AS-BA-1	6-7-8	3-6-10	304-608-1013	30	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
50	MBD-BS-BA-1	8-9-10	3-5.5-9	304-557-912	30	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
51	MBD-CS-BA-1	10-11-12	3-5-8	304-507-811	30	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
52	MBD-DS-BA-1	12-13.5-15	3-4.5-8	304-456-811	30	1800	0.035inch (0.89mm)	≥2.8mm	Supporting wire
53	MBD-AM-BB-2	6-7-8	3-6-10	304-608-1013	55	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire

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54	MBD-BM-BB-2	8-9-10	3-5.5-9	304-557-912	55	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
55	MBD-CM-BB-2	10-11-12	3-5-8	304-507-811	55	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
56	MBD-DM-BB-2	12-13.5-15	3-4.5-8	304-456-811	55	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
57	MBD-EM-BB-2	15-16.5-18	3-4.5-7	304-456-709	55	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
58	MBD-FM-BB-2	18-19-20	3-4.5-6	304-456-608	55	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
59	MBD-AM-BA-2	6-7-8	3-6-10	304-608-1013	55	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
60	MBD-BM-BA-2	8-9-10	3-5.5-9	304-557-912	55	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
61	MBD-CM-BA-2	10-11-12	3-5-8	304-507-811	55	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
62	MBD-DM-BA-2	12-13.5-15	3-4.5-8	304-456-811	55	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
63	MBD-EM-BA-2	15-16.5-18	3-4.5-7	304-456-709	55	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
64	MBD-FM-BA-2	18-19-20	3-4.5-6	304-456-608	55	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire

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65	MBD-AL-BA-2	6-7-8	3-6-10	304-608-1013	80	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
66	MBD-BL-BA-2	8-9-10	3-5.5-9	304-557-912	80	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
67	MBD-CL-BA-2	10-11-12	3-5-8	304-507-811	80	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
68	MBD-DL-BA-2	12-13.5-15	3-4.5-8	304-456-811	80	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
69	MBD-EL-BA-2	15-16.5-18	3-4.5-7	304-456-709	80	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
70	MBD-FL-BA-2	18-19-20	3-4.5-6	304-456-608	80	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
71	MBD-AS-BB-2	6-7-8	3-6-10	304-608-1013	30	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
72	MBD-BS-BB-2	8-9-10	3-5.5-9	304-557-912	30	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
73	MBD-CS-BB-2	10-11-12	3-5-8	304-507-811	30	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
74	MBD-DS-BB-2	12-13.5-15	3-4.5-8	304-456-811	30	2300	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
75	MBD-AS-BA-2	6-7-8	3-6-10	304-608-1013	30	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire

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76	MBD-BS-BA-2	8-9-10	3-5.5-9	304-557-912	30	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
77	MBD-CS-BA-2	10-11-12	3-5-8	304-507-811	30	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire
78	MBD-DS-BA-2	12-13.5-15	3-4.5-8	304-456-811	30	1800	0.035inch (0.89mm)	≥2.8mm	Stainless steel guide wire