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, PRC
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 SRN	DE-AR-000000001
Product Name	Disposable Multistage Dilation Balloon Catheter
Basic UDI-DI	6902284MB45712DP
Catalogue Number	Please refer to Attachment 2
GMDN Code	45712
EMDN Code	G030101
Classification and Rule	Class IIa (According to Annex VIII, Rule 6 of MDR 2017/745)
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
Intended Purpose	The device is designed to be used to dilate strictures of the gastrointestinal tract.

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.

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 details, please 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:	2023-07-18
Certificate Expiry Date:	2027-09-01

Signature: Place and date of issue:

Becky Li ..... Nanjing, 2024-09-18

Name: Becky Li
Position: Person Responsible for Regulatory Compliance

Attachment 1

- ✧ Medical Device Regulation (EU) 2017/745
- ✧ EN ISO 13485-2016+A11-2021 Medical devices – Quality management systems- Requirements for regulatory purposes
- ✧ EN ISO 14971-2019+AMD11-2021 Medical devices - Application of risk management to medical devices
- ✧ ISO/TR 24971: 2020 Medical devices - Guidance on the application of ISO 14971
- ✧ EN ISO 15223-1: 2021 Medical devices— Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
- ✧ EN ISO 80369-7: 2021 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications
- ✧ EN 62366-1-2015+AMD1:2020 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
- ✧ ISO 8600-4: 2014 Optics and optical instruments Medical endoscope and endoscopic accessories - Part 4: insert part and the determination of maximum width
- ✧ EN ISO 10993-5:2009, Biological evaluation of medical devices - Part 6: Tests for in vitro cytotoxicity
- ✧ EN ISO 10993-7:2008/A1:2022 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants
- ✧ EN ISO 10993-10:2013 Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity.
- ✧ EN ISO 11135:2014+A1:2019 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
- ✧ EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ✧ EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ✧ ISTA 2A:2011 Packaged-Products 150lb (68kg) or less ISTA 2A Series Partial Simulation Performance Test Procedure
- ✧ MEDDEV 2.7.1 (Rev. 4) Guidelines on Medical Devices Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies

- ✧ EN ISO 10555-1 2013+A1-2017 Intravascular catheters. Sterile and single-use catheters. Part 1: General requirements
- ✧ EN ISO 10555-4:2013 Intravascular catheters. Sterile and single-use catheters. Part 4: Balloon dilatation catheters
- ✧ ASTM F 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ✧ MEDDEV 2.12/2 (Rev. 2) Post Market Clinical Follow-Up Studies a Guide for Manufacturers and Notified Bodies
- ✧ MDCG 2020-5 Guidance on clinical evaluation – Equivalence
- ✧ MDCG 2020-6 Guidance on sufficient clinical evidence for legacy devices
- ✧ MDCG 2020-7 Guidance on PMCF plan template

Attachment 2

NO	REF	NO	REF	NO	REF
1	MBD-AM-BB-2	2	MBD-BM-BB-2	3	MBD-CM-BB-2
4	MBD-DM-BB-2	5	MBD-EM-BB-2	6	MBD-FM-BB-2
7	MBD-AM-BA-2	8	MBD-BM-BA-2	9	MBD-CM-BA-2
10	MBD-DM-BA-2	11	MBD-EM-BA-2	12	MBD-FM-BA-2
13	MBD-AL-BA-2	14	MBD-BL-BA-2	15	MBD-CL-BA-2
16	MBD-DL-BA-2	17	MBD-EL-BA-2	18	MBD-FL-BA-2
19	MBD-FL-BB-2	20	MBD-AS-BB-2	21	MBD-BS-BB-2
22	MBD-CS-BB-2	23	MBD-DS-BB-2	24	MBD-AS-BA-2
25	MBD-BS-BA-2	26	MBD-CS-BA-2	27	MBD-DS-BA-2

Revision History

Revision	Date	Description
A/0	2024-08-15	Initial