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) Eiffestrasse 80, 20537 Hamburg, Germany
Product name	Extraction Basket / short-wire compatible
Model Number	Please see Attachment 2
UMDNS Code	15629
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. We are exclusively responsible for the Declaration of Conformity.

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)

Attachment 1

Notified Body:	TUV Product Service GmbH, Ridlerstr. 65, 80339 MUnchen, Germany
Identification number:	0123
Certificate Number:	G1 0488500047
Expire date of the certificate:	2028-12-31
Place, Date of Certificate:	Nanjing, 2019-5-17

Signature: Frank Liu **Date** 2023-07-20

Title: Management Rep

Attachment 1

- ✧ Directive 93/42/EEC concerning medical devices.
- ✧ EN ISO 13485:2016/A11:2021 Medical devices – Quality management systems-Requirements for regulatory purposes
- ✧ EN ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ✧ EN ISO 20417:2021 Information supplied by the manufacturer with medical devices
- ✧ EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ✧ ISO/TR 24971-2020 Medical devices — Guidance on the application of ISO 14971
- ✧ EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing
- ✧ EN ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- ✧ 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 10993-11:2018 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- ✧ EN ISO 11135:2014/A1:2019 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
- ✧ EN ISO 11737-1:2018/A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products Sterilization of medical devices
- ✧ EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ✧ 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
- ✧ ASTM F1886/F1886M-16 Standard test method for determining integrity of seals for flexible packaging by visual inspection
- ✧ ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages

- ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices
- EN ISO 8536-4: 2020 Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)
- EN 62366-1:2015+AMD 1:2020 Medical devices — Part 1: Application of usability engineering to medical devices — Amendment 1
- ISO 8600-1-2015 Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements
- EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness
- EN 17141:2020 Cleanrooms and associated controlled environments — Biocontamination control
- MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI
- MDCG-2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG-2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance
- MDCG 2020-5 Guidance on Clinical Evaluation
- MDCG 2020-6 Guidance on Sufficient Clinical Evaluation
- IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation
- 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

ISO/TR 20416 Medical devices — post-market surveillance for manufacturers

Attachment 2

Product List of Extraction Basket / short-wire compatible

NO.	REF	Basket shape	Basket Diameter (mm)	Working Channel (mm)	Working Length (mm)
1	RSEB-H4-15	Hexagonal four wires	15	≥3.7	2000
2	RSEB-H4-20	Hexagonal four wires	20	≥3.7	2000
3	RSEB-H4-25	Hexagonal four wires	25	≥3.7	2000
4	RSEB-H4-30	Hexagonal four wires	30	≥3.7	2000
5	RSEB-S4-15	Spiral four wires	15	≥3.7	2000
6	RSEB-S4-20	Spiral four wires	20	≥3.7	2000
7	RSEB-S4-25	Spiral four wires	25	≥3.7	2000
8	RSEB-S4-30	Spiral four wires	30	≥3.7	2000