



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)
Representative Eiffestrasse 80, 20537 Hamburg, Germany
Product name Retrieval Balloon / short-wire compatible
Model Number: Please see Attachment 1
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)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
Identification number: 0123
Certificate Number: G1 048850 0047
Expire date of the certificate: 2028-12-31
Place, Date of Certificate: Nanjing, 2018-09-27

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

Title: Management Rep



Attachment 1

Retrieval Balloon / short-wire compatible Product List

No.	REF	Work diameter (mm)	Working Length (mm)	Injection port	Channel diameter (mm)
1	RSRB-T-9-20	9	2000±100	Above	3.2
2	RSRB-T-12-20	12	2000±100	Above	3.2
3	RSRB-T-15-20	15	2000±100	Above	3.2
4	RSRB-T-18-20	18	2000±100	Above	3.2
5	RSRB-T-21-20	21	2000±100	Above	3.2
6	RSRB-T-9/12-20	9/12	2000±100	Above	3.2
7	RSRB-T-12/15-20	12/15	2000±100	Above	3.2
8	RSRB-T-15/18-20	15/18	2000±100	Above	3.2
9	RSRB-T-18/21-20	18/21	2000±100	Above	3.2
10	RSRB-T-9/12/15-20	9/12/15	2000±100	Above	3.2
11	RSRB-T-12/15/18-20	12/15/18	2000±100	Above	3.2
12	RSRB-T-15/18/21-20	15/18/21	2000±100	Above	3.2
13	RSRB-T-9-20-B	9	2000±100	Below	3.2
14	RSRB-T-12-20-B	12	2000±100	Below	3.2
15	RSRB-T-15-20-B	15	2000±100	Below	3.2
16	RSRB-T-18-20-B	18	2000±100	Below	3.2
17	RSRB-T-21-20-B	21	2000±100	Below	3.2
18	RSRB-T-9/12-20-B	9/12	2000±100	Below	3.2
19	RSRB-T-12/15-20-B	12/15	2000±100	Below	3.2
20	RSRB-T-15/18-20-B	15/18	2000±100	Below	3.2
21	RSRB-T-18/21-20-B	18/21	2000±100	Below	3.2
22	RSRB-T-9/12/15-20-B	9/12/15	2000±100	Below	3.2
23	RSRB-T-12/15/18-20-B	12/15/18	2000±100	Below	3.2
24	RSRB-T-15/18/21-20-B	15/18/21	2000±100	Below	3.2