



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 Guidewire Locking Device

Model Number Please see the Attachment

UMDNS Code 11726

Classification I sterile (Annex IX, Rule 1 of MDD 93/42/EEC)

Conformity Assessment Route: Annex V of MDD 93/42/EEC amended by directive 2007/47/EC

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 MUnchen,
Germany

Identification number: 0123

Certificate Number: G2S 048850 0048 Rev. 03

Expire date of the certificate: 2028-12-31

Place, Date of Certificate: Nanjing, 2018-09-27

Signature: 

Date: 2023-07-27

Title: Management Representative

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Attachment**Product List of Guidewire Locking Device**

No.	REF	Endoscopy	Description
1	MT-RGL-O	Olympus/ Fujinon	The Guidewire Locking Device is mounted at the end of the endoscope. In the ERCP operation used to lock the wire and seal the claw.
2	MT-RGL-P	Pentax	The Guidewire Locking Device is mounted at the end of the endoscope. In the ERCP operation used to lock the wire and seal the claw.