FIEGERT-ENDOTECH Medizintechnik GmbH • P.O.-Box 4105 • 78506 Tuttlingen, Germany

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EC-Declaration of Conformity

Manufacturer : Fiegert-Endotech Medizintechnik GmbH
Address: Gänsäcker 42, D - 78532 Tuttlingen, Germany

- reusable medical devices of **class 1**
- according to below product group list
- from manufacturing date: 25.09.2015 / up to manufacturing date: 24.09.2018

Formal declaration

We declare under our sole responsibility that our below listed medical products comply with all the requirements of the Medical Devices Directive 93/42/EEC and the supplementary Directive 2007/47/EC.

Product group list

Product groups – Manufacturer description	UMDNS-No.	Risk class	Rule
Rigid endoscopes without working channel	10-198	1	12
Surgical instruments for endoscopy	11-798	1	6
Light sources and accessories	12-345	1	12
Flexible endoscopes without working channel	12-709	1	12
Trocar sleeves and sheaths without stop cocks	14-154	1	6
Documentation units and accessories	15-748	1	12

Responsible for the readiness of technical documentation is the representative of quality management Mr. Walter Fiegert.

Tuttlingen, 25.09.2015

Walter Fiegert
(General Manager, QM and safety representative) (Signature)

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Geschäftsführer:
Walter Fiegert, Ilse Fiegert
Amtsgericht Stuttgart HRB 450 529
Ust.-Id.-Nr: DE 142940328
Steuer-Nr.: 21101/10606

Kreissparkasse Tuttlingen:
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IBAN DE03 6435 0070 0000 0314 02
BIC-Code: SOLADES1TUT

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EC-Declaration of Conformity

Manufacturer : Fiegert-Endotech Medizintechnik GmbH
Address: Gänsäcker 42, D - 78532 Tuttlingen, Germany

- reusable medical devices of **class 2a**
- according to below product group list
- from manufacturing date: 25.09.2015 / up to manufacturing date: 24.09.2018

Formal declaration

We declare under our sole responsibility that our below listed medical products comply with all the requirements of the Medical Devices Directive 93/42/EEC and the supplementary Directive 2007/47/EC.

Product group list

Product groups – Manufacturer description	UMDNS-No.	Risk class	Rule
Suction-/Irrigation unit	13-845	2a	11
Trocars and Sheaths	15-260	2a	7
Shaver blades for Arthroscopy	17-117	2a	9
Rigid Endoscopes with working channel	17-690	2a	6
Shaver for Arthroscopy	17-918	2a	9

The development, production and sale of the product is being supported by a QM-System according to the requirements of ISO13485 of the law of medical products and the FDA.

The statement is certified by:

EC quality assurance system, certificate registration no.: 44 232 150570, controlled and issued by Notified Body No. 0044, TÜV NORD, Langemarckstr. 20, D-45141 Essen, valid until 24.09.2018.

Responsible for the readiness of technical documentation is the representative of quality management Mr. Walter Fiegert.

Tuttlingen, 25.09.2015

Walter Fiegert
(General Manager, QM and safety representative) (Signature)

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EC-Declaration of Conformity

Manufacturer : Fiegert-Endotech Medizintechnik GmbH
Address: Gänsäcker 42, D - 78532 Tuttlingen, Germany

- reusable medical devices of **class 2b**
- according to below product group list
- from manufacturing date: 25.09.2015 / up to manufacturing date: 24.09.2018

Formal declaration

We declare under our sole responsibility that our below listed medical products comply with all the requirements of the Medical Devices Directive 93/42/EEC and the supplementary Directive 2007/47/EC.

Product group list

Product groups – Manufacturer description	UMDNS-No.	Risk class	Rule
HF-Instruments (Forceps, Scissors, Punches, Electrodes)	11-502	2b	9
Insufflators	16-849	2b	11

The development, production and sale of the product is being supported by a QM-System according to the requirements of ISO13485 of the law of medical products and the FDA.

The statement is certified by:

EC quality assurance system, certificate registration no.: 44 232 150570, controlled and issued by Notified Body No. 0044, TÜV NORD, Langemarckstr. 20, D-45141 Essen, valid until 24.09.2018.

Responsible for the readiness of technical documentation is the representative of quality management Mr. Walter Fiegert.

Tuttlingen, 25.09.2015

Walter Fiegert
(General Manager, QM and safety representative) (Signature)

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