



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

FIEGERT-ENDOTECH Medizintechnik GmbH
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EC-Declaration of Conformity

Manufacturer : Fiebert-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: 25.09.2018 / up to manufacturing date: 24.09.2023

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
Rigid Endoscopes with working channel	17-690	2a	6

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 24.09.2023.

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

Tuttlingen, 25.09.2018

Walter Fiebert
(General Manager, QM and safety representative)

(Signature)


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25.09.2018 – WF
Seite 1/1

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

Kreissparkasse Tuttlingen:
BLZ 643 500 70, Konto 31 402
IBAN DE03 6435 0070 0000 0314 02
BIC-Code: SOLADES1TUT

Deutsche Bank Tuttlingen:
BLZ 653 700 75, Konto 2 183 135
IBAN DE56 6537 0075 0218 3135 00
BIC-Code: DEUT DE 55 603