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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Fiab SpA
Via P. Costoli, 4
Vicchio (FI)
50039
Italy

Digitally signed by Ermicev Alexandr
Date: 2020.03.19 14:24:47 EET
Reason: MoldSign Signature
Location: Moldova

Holds Certificate Number: **MD 77846**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, servicing and retail of the following medical devices and accessories:
- Electronic devices for electrophysiology and temporary cardiac stimulation.
- Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads).
- Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG).
- Introducer kits for percutaneous use.

The stockholding and supply of medical devices, with lot traceability.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-02-25
Latest Revision Date: 2018-07-27

Effective Date: 2018-08-01
Expiry Date: 2021-07-31

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Certificate No: **MD 77846**

Location	Registered Activities
Fiab SpA Via P. Costoli, 4 Vicchio (FI) 50039 Italy	The manufacture of the following medical devices and accessories: - Electronic devices for electrophysiology and temporary cardiac stimulation. - Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads). - Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG). Introducer kits for percutaneous use. The stockholding and supply of medical devices, with lot traceability.
Fiab SpA Via Passerini 2,3,4,6 Vicchio (FI) 50039 Italy	The design, development, manufacture, servicing and retail of the following medical devices and accessories: - Electronic devices for electrophysiology and temporary cardiac stimulation. - Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads). - Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG). Introducer kits for percutaneous use. The stockholding and supply of medical devices, with lot traceability.
Fiab SpA Via Della Resistenza, 18 Vicchio (FI) 50039 Italy	The manufacture and servicing of the following medical devices and accessories: - Electronic devices for electrophysiology and temporary cardiac stimulation. - Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads). - Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG). Introducer kits for percutaneous use. The stockholding and supply of medical devices, with lot traceability.

Original Registration Date: 2004-02-25
Latest Revision Date: 2018-07-27

Effective Date: 2018-08-01
Expiry Date: 2021-07-31

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01906**

Issued To: **Fiab SpA**
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

In respect of:

The design, development and manufacture of sterile leads for transoesophageal cardiac and temperature monitoring, cardiac stimulation, cardiac defibrillation and electrophysiological studies; percutaneous introducers; electronic equipments for oesophageal temperature monitoring, electrophysiological studies and emergency cardiac stimulation; sterile and non sterile electrosurgical electrodes and related accessories; electrodes for defibrillation/pacing; sterile single use neuropacers; sterile single use and reusable electrocauteries and associated accessories; sterile and non sterile, single use and reusable needle electrodes for EEG and EMG.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-05-11** Date: **2018-05-10** Expiry Date: **2023-05-10**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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