

# 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

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

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)