

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 for percutaneous use.
 - Devices for the extraction of permanent intravenous and subcutaneous leads.
- The stockholding and supply of medical devices, with lot traceability.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2004-02-25

Latest Revision Date: 2024-07-26

Effective Date: 2024-08-01

Expiry Date: 2027-07-31

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Certificate No: MD 77846

Location	Registered Activities
Fiab SpA Via P. Costoli, 4 Vicchio (FI) 50039 Italy	Manufacture of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes; non sterile ECG reusable electrodes, electrotherapy reusable accessories, packaging of oxygen therapy accessories. Warehousing and distribution of oxygen therapy accessories, ECG reusable electrodes, electrotherapy reusable accessories.
Fiab SpA Via Passerini 2,3,4,6 Vicchio (FI) 50039 Italy	Via Passerini 2-4-6 – MAIN SITE: Administrative, Design and Development of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes, temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths; non sterile ECG reusable electrodes, electrotherapy reusable accessories, oxygen therapy accessory, external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables, defibrillation electrodes, electrostimulation electrodes and ECG single use electrode. Manufacture of sterile temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths, non-sterile external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables. Final packaging, warehousing and distribution of percutaneous introducers sterile products, sterile temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths. Servicing activities of non-sterile external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor. Via Passerini 3: - LOGISTIC Warehousing and distribution of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes, temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths; non sterile ECG reusable electrodes, electrotherapy reusable accessories, oxygen therapy accessory, external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables, defibrillation electrodes, electrostimulation electrodes and ECG single use electrode.
Fiab SpA Via Della Resistenza, 18 Vicchio (FI) 50039 Italy	Manufacture of non sterile defibrillation electrodes, Storage of oxygen therapy accessories and electrosurgical neutral electrodes and raw material for defibrillation electrodes. Warehousing and distribution of non sterile defibrillation electrodes

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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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Location	Registered Activities
Fiab SpA Via Costoli 6 Vicchio (FI) 50039 Italy	Storage of components and assemblies for oxygen therapy and electrosurgery.
Fiab SpA Via Barducci 13 Vicchio (FI) 50039 Italy	Storage of components and assemblies for oxygen therapy and electrosurgery.
Fiab SpA Via Giugni 8 Vicchio Firenze 50039 Italy	Design and Development of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes, temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths; non sterile ECG reusable electrodes, electrotherapy reusable accessories, oxygen therapy accessory, external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables, defibrillation electrodes, electrostimulation electrodes and ECG single use electrode. Manufacture of non-sterile electrostimulation electrodes and ECG single use electrodes. Warehousing and distribution of non-sterile electrostimulation electrodes and ECG single use.

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