By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Manufacturer: Fiab SpA

Address:
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

Single Registration Number: IT-MF-000005988

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-11-17**

Current Issue Date: **2025-08-20**

Starting Validity Date: **2025-08-20**

Expiry Date: **2026-11-16**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
External temporary cardiac stimulators dual chamber External temporary cardiac stimulators single chamber	See MDR 823996
MYOPACE® - epimyocardial pacing wires for temporary cardiac stimulation	See MDR 747885
Endocardial Leads for Temporary Pacing and Electrophysiological Studies	See MDR 823997

Class IIb	Intended purpose
Esophageal temperature monitoring system, including sterile probes and connecting cables.	Intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms.
External cardioversion defibrillation electrode pads.	Disposable multifunction electrodes intended for: - Transthoracic external defibrillation. - Transthoracic synchronized cardioversion. - Transthoracic ECG Monitoring. - Temporary transthoracic cardiac pacing (non-invasive).
Single use surgical instruments and neutral electrodes for use in electrosurgery.	Single use, sterile and non-sterile, handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.
Reusable surgical instruments and neutral electrodes for use in electrosurgery.	Reusable handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Instruments for diathermocoagulation.	Reusable and sterile single-use handpieces and electrodes, intended for cauterisation of soft tissues and small blood vessels in surgical procedures.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Accessories for oxygentherapy and aerosoltherapy.	Class IIa
Transesophageal arrhythmology devices.	Class IIa
Cardiocirculatory introducers	Class IIa
Non implantable cardiac stimulators – hardware	Class Is
Cleaning pads and holsters for electrosurgery	Class Is
Accessory for percutaneous dilator sheaths	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-17	3415341	Issued
2023-01-23	3792161	Amended – Removal of subcontractor pages. Supplemented – addition of device group "Esophageal temperature monitoring system, including sterile probes and connecting cables". Supplemented – addition of device category "Accessories for oxygentherapy and aerosoltherapy.".
2023-04-06	3872133	Supplemented – addition of device group "External cardioversion defibrillation electrode pads.".
2024-10-09	30076890	Amended – Editorial amendment, with no change in scope, to the wording of the intended use of device group "External cardioversion defibrillation electrode pads". Supplemented – Addition of device group "Single use surgical instruments and neutral electrodes for use in electrosurgery". Supplemented – Addition of device group "Reusable surgical instruments and neutral electrodes for use in electrosurgery". Supplemented – Addition of device category "Instruments for diathermocoagulation". Supplemented – Addition of device category "Transesophageal arrhythmology devices".
2025-03-27	30377373	Supplemented – Addition of External temporary cardiac stimulators dual chamber and MYOPACE® - epimyocardial pacing wires for temporary cardiac stimulation. Addition of device category - Cardiocirculatory introducers.

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Date	Reference Number	Action
Current	30447766	Supplemented – Addition of Endocardial Leads for Temporary Pacing and Electrophysiological Studies and External Temporary Cardiac Stimulators Single Chamber.

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