

# EU Quality Management System Certificate

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

## MDR 747884 R000

**Manufacturer:** Fiab SpA

**Address:**

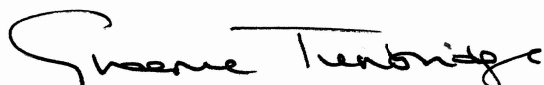
Via P. Costoli, 4  
Vicchio  
Firenze  
50039  
Italy

**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 and Class IIb implantable devices an 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 Medical Devices

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

Current Issue Date: **2023-01-23**

Starting Validity Date: **2023-01-23**

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

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### Device Schedule: Class III and Class IIb devices

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.

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

Device(s)	Risk Classification
Accessories for oxygenotherapy and aerosoltherapy.	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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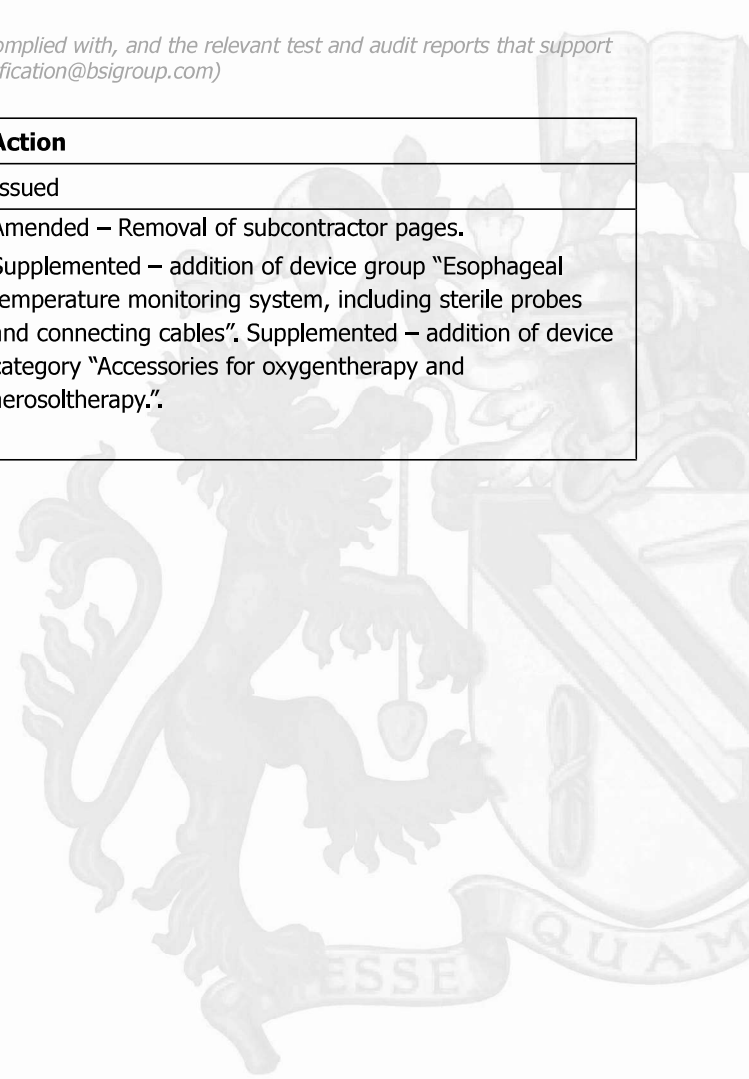
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### Certificate History

(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](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2021-11-17	3415341	Issued
Current	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.”.



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