By Royal Charter

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:

See certificate scope page.

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):

Gary Fenton, Global Assurance Director

First Issued: **11 May 1998** Date: **22 September 2014** Expiry Date: **10 May 2018**

...making excellence a habit.™

By Royal Charter

Certificate No: CE 01906

Certificate Scope:

The design, development and manufacture of sterile leads for transoesophageal cardiac and temperature monitoring, cardiac stimulation and cardiac defibrillation, percutaneous introducers; devices for electrophysiological studies, oesophageal temperature monitoring 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 accessories for EEG and EMG.

First Issued: **11 May 1998** Date: **22 September 2014** Expiry Date: **10 May 2018**

...making excellence a habit.™