



Certificate

Full Quality Assurance

No. CE 01906



Issued to:

Fiab SpA
Via P Costoli, 4
50039 Vicchio
Firenze
Italy

In respect of:

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.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

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: **7 May 2013**

Expiration Date: **10 May 2018**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

...making excellence a habit.™