

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:

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

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **1998-05-11**

Date: **2019-03-12**

Expiry Date: **2023-05-10**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.