EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 510679**

Issued To: **Fiab SpA**
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

In respect of:

The manufacture of sterile and non sterile nasal cannulae, masks, kits and accessories for oxygen and aerosol therapy.
Those aspects of Annex V related to securing and maintaining sterility in the manufacture of femoral compression discs, connection cables, touch-proof plug adaptors, heart wire insulators, electrosurgical pencil holster and cleaning pad for electrosurgical pencil, handle for extraction of permanent intravenous and subcutaneous leads.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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

Albert Roossien, Regulatory Lead

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