

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
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50039
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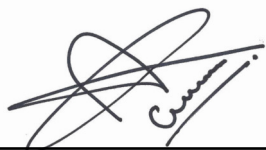
In respect of:

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

First Issued: **2006-10-03**

Date: **2019-03-12**

Expiry Date: **2021-10-02**

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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.