DICHIARAZIONE CE DI CONFORMITÀ in accordo alla Direttiva 93/42/CEE

EC DECLARATION OF CONFORMITY according to 93/42/EEC Directive

(Rif./*Ref.* NQ-04-01)

Vicchio, 8 Novembre 2019
Vicchio, 8 November 2019

La società FIAB SpA, con sede in via P. Costoli, 4 - 50039 Vicchio (FI),
nella persona del Presidente del Consiglio d'Amministrazione Alberto Calabrò,
FIAB SpA having its headquarters at 50039 Vicchio (FI), Via P. Costoli 4,
in the person of the President of the Board Alberto Calabrò,

dichiara, sotto la propria responsabilità, che i dispositivi
declares, under its own responsibility, that the devices

Piastre riutilizzabili di riferimento bipartite per elettrochirurgia, modelli:
Reusable split electrosurgical grounding plates, models:

F7930

inclusi nel Master File MF 116 */ part of Master File MF 116*

sono conformi ai requisiti della Direttiva 93/42/CEE (DLgs. 46/97) e successive modifiche,
comply with the requirements of 93/42/EEC Directive, including amendments,

appartengono alla Classe IIb / *are Class IIb products,*

codice GMDN **42551**,
codice CND **Z12010980**,

non contengono sostanze medicinali né elementi di origine animale,
do not contain drug substances or elements of animal origin,

che è stata seguita la procedura per la valutazione della conformità descritta in Allegato II della suddetta direttiva,
that FIAB has followed the conformity assessment procedure described in Annex II of the above-mentioned directive,

come riportato sul certificato CE n°CE 01906 rilasciato da British Standard Institution (O.N. n°2797),
as described in the EC Certificate No.CE 01906 issued by British Standard Institution (N.B. No.2797),

che sono state seguite le procedure di gestione del sistema di qualità FIAB secondo ISO 13485,
Certificato di Registrazione n°MD 77846 rilasciato da BSI,
that the procedures of FIAB quality system management according to ISO 13485 have been followed,
Certificate of Registration No.MD 77846 issued by BSI,

che sono state applicate, tra le altre, le seguenti norme armonizzate:
that, among the others, the following standards were applied:

EN 60601-1, 2006/A1:2013 - EN 60601-2-2, 2009 - EN ISO 15223-1, 2016 - EN ISO 14971, 2012 - EN ISO 10993-1, 2009 - EN 1041, 2008

e che non contengono lattice / *and that they are Latex-free*

CE001/116

Prima emissione/*First Issued:* 06/03/2002
Ultima revisione/*Last Issued:* 08/11/2019

FIAB SpA
Presidente del C.d.A
President of the Board
Alberto Calabrò

Cod. 99500036MD4J pagina 1/1

Digitally signed by Ermicev Alexandr
Date: 2023.09.18 20:28:19 EEST
Reason: MoldSign Signature
Location: Moldova

bsi.

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:

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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