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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-05-11** Date: **2018-05-10** Expiry Date: **2023-05-10**

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BSI

CE SERTIFIKATAS - Visiškas Kokybės Užtikrinimas

Europos Tarybos Direktyva 93/42/EEC, Priedas II, Dalis 4

Nr. CE 01906

Kam išduota:

FIAB SpA
Via P. Costoli, 4
Vicchio
Firenze
50039
Italija

Dėl:
Kūrimo, projektavimo ir gamybos sterilių zondų perstempliniams širdies stebėjimams, stimuliacijai ir defibriliacijai; prietaisų elektrofiziologiniams tyrimams ir ekstrinei širdies stimuliacijai; sterilių ir nesterilių kaniulių, kaukių, rinkiniams ir priemonių deguonies terapijai, sterilių ir nesterilių elektrochirurginių rankenų antgaliai, elektrodai ir susijusių priemonių, sterilių vienkartinių neurostimuliatorių ir elektrokauterių

Remiantis mūsų atliktais patikrinimais pagal Europos Tarybos Direktyvą 93/42/EEC, Priedą II, Dalį 4.

Britų Standartų Institutas - įgaliota ir Notifikuotoji įstaiga aukščiau minėtai Direktyvai (Notifikuotos įstaigos numeris 0086):

(parašas)

_____

Stewart Brain, Kokybės vadovas

Pirmoji sertifikavimo data: 1998 gegužės 11d.

Šio sertifikato data: 2018 gegužės 10 d.

Galioja iki: 2023 gegužės 10d.

(rekvizitai)

Vicchio (FI), 12/04/2023

TO WHOM IT MAY CONCERN

Subject: Extension of the MDR 2017/745 transitional period – confirmation of validity of FIAB MDD 93/42/EEC Certificates CE 01906, CE 649635, CE 720326

The amendment of the Medical Devices regulation (MDR) 2017/745 introduced by the *Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* (**Attachment 1** of this letter) aims – among other things – to give Manufacturers and Notified Bodies sufficiently more time to carry out, in accordance with the MDR, the conformity assessment of devices covered by a certificate issued in accordance with Medical Devices Directive (MDD) 93/42/EEC that is going to expire or is already expired.

Such devices, also known as 'legacy devices' can benefit from an extended transitional period as set in the Regulation (EU) 2023/607, for the application of MDR.
'Legacy devices' should be understood as devices, which, in accordance with the MDR's transitional provisions, are placed on the market after the MDR's date of application (i.e. 26 May 2021) if certain conditions are fulfilled. Those devices covered by a valid EC certificate issued in accordance with MDD prior to 26 May 2021benefit of an extension of the transitional period beyond 26 May 2024 if the conditions laid down in Article 120(3c) MDR are fulfilled, for the relevant certificates expired or going to expire after 20 March 2023.

As the Manufacturer of the medical devices listed in **Attachment 2** of this letter, FIAB SpA herewith confirms that the products covered by the following MDD 93/42/EEC certificates

- CE 01906, MDD Annex II.3 (Full Quality Assurance system certificate)
- CE 649635, CE 720326 MDD Annex II.4 (Design Dossier Examination certificate)

fulfil the requirements defined by Regulation (EU) 2023/607.
Consequently, the above mentioned certificates can be considered as valid, respectively, until 31/12/2028 for class IIa and class IIb medical devices (CE 01906) and until 31/12/2027 for class III medical devices (CE 649635, CE 720326), when FIAB SpA continues to comply with the relevant requirements in Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607.

The confirmation is made taking into account the following aspects

- Regulation (EU) 2023/607 extends the validity of CE certificates under MDD, considering limited capacity of Notified Bodies accredited for conformity assessment procedures under MDR
- Important condition of this extension is that the Manufacturer shall submit an MDR certification application for these devices to a MDR Notified Body not later than 26/05/2024 and shall sign MDR certification agreement with the MDR Notified Body no later than 26/09/2024
- Other requirements for this extension includes e.g.: the devices continue to comply with MDD there are no significant changes in the design and intended purpose; devices do not present an unacceptable risk to the health or safety; the Manufacturer has put in place a quality management system in accordance with MDR; a Notified Body is still performing surveillance activity

FIAB SpA is providing appropriate evidences demonstrating that the relevant requirements in Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607 have been fulfilled by now. In particular

- for each of the medical devices listed in **Attachment 2** of this letter, an MDR certification application was already submitted by FIAB to the MDR Notified Body 2797 (BSI) and the respective MDR certification agreement has been signed, as listed in Attachment 2;
- the devices continue to comply with MDD, according to the surveillance activity performed by the same Notified Body 2797 to FIAB; this ensures that there are no significant changes and the devices do not present an unacceptable risk;
- FIAB has already put in place a quality management system in accordance with MDR, as attested by the EU Quality Management System Certificate, MDR 747884 in **Attachment 3**, according to MDR Annex IX chapter I and III. Such MDR certificate already cover the medical devices for which the Notified Body 2797 completed the certification assessment

Francesco Batistini
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Person Responsible for Regulatory Compliance
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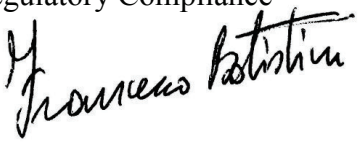

Vicchio (FI), 2023 04 12

VISIEMS, KAM TAI GALI BŪTI AKTUALU

Tema: MDR 2017/745 pereinamojo laikotarpio pratęsimas - FIAB MDD 93/42/EEB sertifikatų CE 01906, CE 649635, CE 720326 galiojimo patvirtinimas

Medicinos prietaisų reglamento (MDR) 2017/745 pakeitimu, padarytu *2023 m. kovo 15 d. Europos Parlamento ir Tarybos reglamentu (ES) 2023/607, kuriuo iš dalies keičiamos reglamentų (ES) 2017/745 (MDR) ir (ES) 2017/746 (IVDR) nuostatos dėl pereinamojo laikotarpio nuostatų, susijusių su tam tikrais medicinos prietaisais ir in vitro diagnostikos medicinos prietaisais* (šio laiško **1 priedas),** siekiama, be kita ko, suteikti gamintojams ir notifikuotosioms įstaigoms pakankamai daugiau laiko, prietaisų, kuriems taikomas pagal Medicinos prietaisų direktyvą (MDD) 93/42/EEB išduotas sertifikatas, kurio galiojimas baigsis arba jau baigėsi, atitikties vertinimą pagal MDR.

Tokiems prietaisams, dar vadinamiems "senaisiais prietaisais", gali būti taikomas Reglamente (ES) 2023/607 nustatytas ilgesnis pereinamasis laikotarpis MDR taikyti.
"Senosios priemonės" turėtų būti suprantamos kaip priemonės, kurios, vadovaujantis MDR pereinamojo laikotarpio nuostatomis, pateikiamos rinkai po MDR taikymo pradžios datos (t. y. 2021 m. gegužės 26 d.), jei įvykdomos tam tikros sąlygos. Tiems prietaisams, kuriems taikomas galiojantis EB sertifikatas, išduotas pagal MDD iki 2021 m. gegužės 26 d., pereinamasis laikotarpis gali būti pratęstas po 2024 m. gegužės 26 d., jei įvykdomos MDR 120 straipsnio 3c dalyje nustatytos sąlygos dėl atitinkamų sertifikatų, kurių galiojimo laikas baigėsi arba baigsis po 2023 m. kovo 20 d.

Kaip šio laiško **2 priede** išvardytų medicinos prietaisų gamintojas, FIAB SpA patvirtina, kad gaminiai, kuriems išduoti šie MDD 93/42/EEB sertifikatai

- CE 01906, MDD II.3 priedas (Visiško kokybės užtikrinimo sistemos sertifikatas)
- CE 649635, CE 720326 MDD II.4 priedas (Projekto dokumentų rinkinio tyrimo

sertifikatas) atitinka Reglamente (ES) 2023/607 nustatytus reikalavimus.
Todėl pirmiau minėti sertifikatai gali būti laikomi galiojančiais atitinkamai iki 2028 m. gruodžio 31 d. IIa ir IIb klasės medicinos prietaisams (CE 01906) ir iki 2027 m. gruodžio 31 d. III klasės medicinos prietaisams (CE 649635, CE 720326), kai "FIAB SpA" ir toliau atitinka atitinkamus Reglamento (ES) 2017/745 su pakeitimais, padarytais Reglamentu (ES) 2023/607, reikalavimus.

Patvirtinimas atliekamas atsižvelgiant į šiuos aspektus

- Reglamentu (ES) Nr. 2023/607 pratęsiamas CE sertifikatų galiojimas pagal MDD, atsižvelgiant į ribotus paskelbtųjų įstaigų, akredituotų atitikties vertinimo procedūroms pagal MDR, pajėgumus.
- Svarbi šio pratęsimo sąlyga yra ta, kad gamintojas ne vėliau kaip 2024-05-26 turi pateikti MDR notifikuotajai įstaigai šių prietaisų MDR sertifikavimo paraišką ir ne vėliau kaip 2024-09-26 turi pasirašyti MDR sertifikavimo sutartį su MDR notifikuotąja įstaiga.
- Kiti reikalavimai šiam pratęsimui: prietaisai ir toliau atitinka MDD, nėra reikšmingų konstrukcijos ir paskirties pakeitimų, prietaisai nekelia nepriimtino pavojaus sveikatai ar saugai, gamintojas įdiegė kokybės valdymo sistemą pagal MDR, notifikuotoji įstaiga vis dar atlieka priežiūros veikla.

"FIAB SpA" pateikia tinkamus įrodymus, kad atitinkami Reglamento (ES) 2017/745 su pakeitimais, padarytais Reglamentu (ES) 2023/607, reikalavimai jau įvykdyti. Visų pirma

- FIAB jau pateikė paraišką dėl kiekvieno iš šio rašto **2 priede** išvardytų medicinos prietaisų MDR sertifikavimo 2797 notifikuotajai įstaigai (BSI) ir pasirašė atitinkamą MDR sertifikavimo sutartį, kaip nurodyta 2 priede;
- prietaisai ir toliau atitinka MDD pagal tos pačios notifikuotosios įstaigos 2797 FIAB atliktą priežiūros veiklą; taip užtikrinama, kad nėra reikšmingų pokyčių ir prietaisai nekelia nepriimtinos rizikos;
- FIAB jau yra įdiegusi kokybės valdymo sistemą pagal MDR, tai patvirtina ES kokybės valdymo sistemos sertifikatas, MDR 747884, pateiktas **3 priede,** pagal MDR IX priedo I ir III skyrius. Toks MDR sertifikatas jau taikomas medicinos prietaisams, kurių sertifikavimo vertinimą atliko notifikuotoji įstaiga 2797

Francesco Batistini
Kokybės užtikrinimo vadybininkas
Už teisės aktų laikymąsi atsakingas asmuo FIAB
S.p.A.

el. paštas
quality@fiab.it tel.
+39 055 8497943

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Manufacturer: Fiab SpA

Address:
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

Single Registration Number: IT-MF-000005988

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-11-17**

Current Issue Date: **2023-04-06**

Starting Validity Date: **2023-04-06**

Expiry Date: **2026-11-16**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Esophageal temperature monitoring system, including sterile probes and connecting cables.	Intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms.
External cardioversion defibrillation electrode pads.	The disposable multifunction electrodes FIAB EURODEFIPADS® are indicated for: • Transthoracic external defibrillation. • Transthoracic synchronized cardioversion. • Transthoracic ECG Monitoring. • Temporary transthoracic cardiac pacing (non-invasive). FIAB disposable multifunction electrodes allow the user to effectively operate in the treatment of rhythm disorders related to the above-mentioned applications, without the risk of accidental electrocution related to the use of normally available reusable paddles.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Accessories for oxygentherapy and aerosoltherapy.	Class IIa
Non implantable cardiac stimulators – hardware	Class Is
Cleaning pads and holsters for electrosurgery	Class Is
Accessory for percutaneous dilator sheaths	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issue Date: **2021-11-17**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-17	3415341	Issued
2023-01-23	3792161	Amended – Removal of subcontractor pages. Supplemented – addition of device group "Esophageal temperature monitoring system, including sterile probes and connecting cables". Supplemented – addition of device category "Accessories for oxygentherapy and aerosoltherapy.".
Current	3872133	Supplemented – addition of device group "External cardioversion defibrillation electrode pads.".

First Issue Date: **2021-11-17**

Current Issue Date: **2023-04-06**

Starting Validity Date: **2023-04-06**

Expiry Date: **2026-11-16**

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