Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. _____

Solicitantul Labromed Laborator SRL, cu sediul str. Trandafirilor, 15, Chisinau,
(adresa)
tel./fax: (022) 000 824, e-mail labromed.laborator@gmail.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- ELECTROD CHIRURGICAL, model Neutral electrode F7805W/V
- ELECTROD CHIRURGICAL, model Neutral electrode F7805W/6.3

Se anexează următoarele acte:
a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
b) certificatul de conformitate CE valabil pentru dispozitivele fabricate, după caz;
c) actul prin care producătorul își desemnează reprezentantul.

Data 01.10.2023

Semnătura

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Ermicev Alexandr
Date: 2023.09.30 13:01:21 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Labromed Laborator SRL, cu sediul str. Trandafirilor, 15, Chisinau,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

ELECTROD CHIRURGICAL, model Neutral electrode F7805W/V
ELECTROD CHIRURGICAL, model Neutral electrode F7805W/6.3

Sunt autentice şi corespund realităţii.

Ermicev Alexandr, Director
Numele, prenumele şi funcţia

REPUBLICA MOLDOVA SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. LABROMED LABORATOR IDNO 1012600...

Semnătura

Data 01.10.2023

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

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

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

Vicchio, 02 Luglio 2020
Vicchio, 02 July 2020

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

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

Piastre monouso di riferimento monopartite con cavo di collegamento per elettrochirurgia, modelli:
Disposable non-split electrosurgical grounding plates with connection cable, models:

F7805W/V, F7805PW/V, F7805NW/V, F7805W/6.3, F7805W/6.3-5, F7805PW/6.3-5

inclusi nel Master File MF 106 */ part of Master File MF 106*
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 **11500**,
codice CND **K02010201**,

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

che и stata seguita la procedura per la valutazione della conformita 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 qualita 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 60601-2-2, 2009 - EN ISO 15223-1, 2016 - EN ISO 10993-1, 2009 - EN 1041, 2008 - EN ISO 14971, 2012

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

CE003-106

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

Prima emissione/*First Issued:* 04/07/2003
Ultima revisione/*Last Issued:* 02/07/2020

Cod 99500132MD4E

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MD77846
ISO 13485

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**

"making excellence a habit."

FIAB SpA
Via P. Costoli 4,
Vicchio
Firenze
50039
Italy
06 June 2023

Notified Body Confirmation Letter

Reference: EU2023-607/634403

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

FIAB SpA
Via P. Costoli 4,
Vicchio
Firenze
50039
Italy
SRN Number: IT-MF-000005988

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Giorgia Romeo

Digitally signed by Giorgia Romeo
Date: 2023.06.06 17:20:13 +02'00'

Giorgia Romeo

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Esophageal Leads Esophageal leads for transesophageal electrophisiology studies and cardioversion	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
External cardiac stimulator "Easypace" single chamber	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
External temporary pacemaker – dual chamber (model "1797")	Class III	N/A	CE01906, exp 10 May 2023, NB # 2797
Single chamber external temporary pacemaker "1748"	Class III	N/A	CE01906, exp 10 May 2023, NB # 2797
Sterile single use electrosurgical electrodes Sterile single use electrosurgical pencils Reusable extensions for electrosurgery Reusable electrodes for electrosurgery Sterile single use electrosurgical kits- Reusable electrosurgical pencils Non-sterile single-use electrosurgical pencils Non-sterile single-use electrosurgical electrodes Non-sterile single-use electrosurgical kits	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
Sterile single use tips for reusable cauteries Sterile single use electrocauteries Reusable electrocauteries	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
Sterile single use epicardial wires "Myopace" (mono and bipolar, quadripolar)	Class III	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 CE 649635 (Annex II.4) exp 26 May 2024, NB # 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Rostock Filter	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
Nerve stimulator "Neuropacer" single use, sterile	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
Needles for EMG and EEG, single use Needles for EMG and EEG, reusable	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
Esophageal temperature monitor Connection cable for esophageal temperature monitor and probe Esophageal temperature probe	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797 (MDR 747884 issued on 23 Jan, 2023, NB # 2797)
Single use electrosurgical neutral electrodes, single section Single use electrosurgical neutral electrodes, dual section Reusable electrosurgical neutral electrodes	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
Temporary cardiac pacing leads "Spike" – bipolar, tripolar, tetrapolar, multipolar	Class III	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 CE 649635 (Annex II.4) exp 26 May 2024, NB # 2797
Sterile lead introducer set peel-away Sterile hemostasis valve introducer kit	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
"Extra Safe" dilator sheaths	Class III	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 CE 720326 (Annex II.4) exp 26 May 2024, NB # 2797
External cardioversion defibrillation electrodes	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 (MDR 747884 issued on 6 Apr, 2023, NB # 2797)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/06/06	Initial issue

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

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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
Quality Assurance Manager
Person Responsible for Regulatory Compliance
FIAB S.p.A.

e-mail quality@fiab.it
tel +39 055 8497943

Francesco Batistini

ATTACHMENT 1 to FIAB LETTER
"Extension of the MDR 2017/745 transitional period – confirmation of validity of FIAB MDD 93/42/EEC Certificates"

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Regulations (EU) 2017/745 [3] and (EU) 2017/746 [4] of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC [5] and 93/42/EEC [6] and Directive 98/79/EC of the European Parliament and of the Council [7], such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council [8], while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

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[1] Opinion of 24 January 2023 (not yet published in the Official Journal).

[2] Position of the European Parliament of 16 February 2023 (not yet published in the Official Journal) and decision of the Council of 7 March 2023.

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[4] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

[5] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

[6] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

[7] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

[8] Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 1).

(3) Also due to the impact of the COVID-19 pandemic, the transitional period provided for in Regulation (EU) 2017/746 was already extended by Regulation (EU) 2022/112 of the European Parliament and of the Council (*).

(4) Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, in particular when the complexity of those new requirements is taken into account. Therefore, it is very likely that many devices that can lawfully be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 will not be certified in accordance with that Regulation before the end of the transitional period, which leads to the risk of shortages of medical devices in the Union.

(5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The extension should be of sufficient duration to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.

(6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.

(7) To ensure a progressive transition to Regulation (EU) 2017/745, the appropriate surveillance regarding devices benefiting from the transitional period should eventually be transferred from the notified body that issued the certificate in accordance with Directive 90/385/EEC or Directive 93/42/EEC to a notified body designated under Regulation (EU) 2017/745. For reasons of legal certainty, the notified body designated under Regulation (EU) 2017/745 should not be responsible for conformity assessment and surveillance activities carried out by the notified body that issued the certificate.

(8) As regards the period needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/745 of medical devices that are covered by a certificate or a declaration of conformity that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, a balance should be struck between the limited available capacity of notified bodies and ensuring a high level of patient safety and public health protection. Therefore, the length of the transitional period should depend on the risk class of the medical devices concerned, so that the period is shorter for devices belonging to a higher risk class and longer for devices belonging to a lower risk class.

(9) Contrary to Directives 90/385/EEC and 93/42/EEC, Regulation (EU) 2017/745 requires the involvement of a notified body in the conformity assessment of class III custom-made implantable devices. Due to insufficient notified body capacity and the fact that manufacturers of custom-made devices are often small or medium-sized enterprises which lack access to a notified body under Directives 90/385/EEC and 93/42/EEC, a transitional period should be provided for, during which class III custom-made implantable devices can lawfully be placed on the market or put into service without a certificate issued by a notified body.

(*) Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3).

(10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available on the market or putting into service of devices which are placed on the market by the end of the applicable transitional period and which are still in the supply chain one year after the end of that transitional period. To prevent the unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of such devices, such further making available on the market or putting into service of such devices should be unlimited in time.

(11) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.

(12) Since the objectives of this Regulation, namely to address risks of shortages of medical devices and *in vitro* diagnostic medical devices in the Union, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union ('TEU'). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(13) This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of medical devices and the associated risk of a public health crisis. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2024, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*. For the same reasons, it is also considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(1) Article 120 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

'Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices. Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until the dates set out in paragraph 3a of this Article only if one of the following conditions is fulfilled:

(a) before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

(b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.';

(b) paragraph 3 is replaced by the following:

'3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

3d. By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC.

3e. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3a of this Article shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3c, point (e), of this Article shall be responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 42 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.

3f. By way of derogation from Article 5, class III custom-made implantable devices may be placed on the market or put into service until 26 May 2026 without a certificate issued by a notified body in accordance with the conformity assessment procedure referred to in Article 52(8), second subparagraph, provided that no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.';

(c) paragraph 4 is replaced by the following:

'4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices lawfully placed on the market from 26 May 2021 pursuant to paragraphs 3, 3a, 3b and 3f of this Article, may continue to be made available on the market or put into service.';

(2) Article 122 is amended as follows:

(a) in the first paragraph, the introductory wording is replaced by the following:

'Without prejudice to Article 120(3) to (3e) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2021, with the exception of:';

(b) the second paragraph is replaced by the following:

'As regards the devices referred to in Article 120(3) to (3e) and (4) of this Regulation, the Directives referred to in the first paragraph of this Article shall continue to apply to the extent necessary for the application of those paragraphs.';

(3) in Article 123(3), point (d), the 24th indent is replaced by the following:

'— Article 120(3d).'.

Article 2

Amendments to Regulation (EU) 2017/746

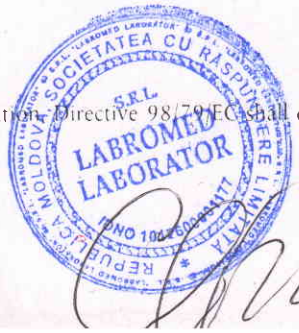
Regulation (EU) 2017/746 is amended as follows:

(1) in Article 110, paragraph 4 is replaced by the following:

'4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022, and devices lawfully placed on the market from 26 May 2022 pursuant to paragraph 3 of this Article may continue to be made available on the market or put into service.';

(2) in Article 112, the second paragraph is replaced by the following:

'As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply to the extent necessary for the application of those paragraphs.'.



Article 3

Entry into force

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 15 March 2023.

For the European Parliament
The President
R. METSOLA

For the Council
The President
J. ROSWALL

ATTACHMENT 2 to FIAB LETTER
"Extension of the MDR 2017/745 transitional period – confirmation of validity of FIAB MDD 93/42/EEC Certificates"

List of FIAB medical devices for which the extension of the MDR transitional period applies

Medical devices group description	MDD 93/42/EEC CE certificate(s)	expiry	MDR certification agreement with Notified Body 2797 (BSI)
Esophageal Leads Esophageal leads for transesophageal electrophisiology studies and cardioversion	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
External cardiac stimulator "Easypace" single chamber	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
External temporary pacemaker – dual chamber (model "1797")	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
Single chamber external temporary pacemaker "1748"	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Sterile single use electrosurgical electrodes Sterile single use electrosurgical pencils Reusable extensions for electrosurgery Reusable electrodes for electrosurgery Sterile single use electrosurgical kits- Reusable electrosurgical pencils	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q624346 (16/02/2022)
Sterile single use tips for reusable cauteries Sterile single use electrocauteries Reusable electrocauteries	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) Amended by Contract Q640589 (24/05/2022)
Sterile single use epicardial wires "Myopace" (mono and bipolar, quadripolar)	CE 01906 Annex II.3 CE 649635 Annex II.4	10/05/2023 26/05/2024	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
Rostock Filter	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Nerve stimulator "Neuropacer" single use, sterile	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Needles for EMG and EEG, single use Needles for EMG and EEG, reusable	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Esophageal temperature monitor Connection cable for esophageal temperature monitor and probe Esophageal temperature probe	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q624346 (16/02/2022)
Single use electrosurgical neutral electrodes, single section Single use electrosurgical neutral electrodes, dual section Reusable electrosurgical neutral electrodes	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021)
Temporary cardiac pacing leads "Spike" – bipolar, tripolar, tetrapolar, multipolar	CE 01906 Annex II.3 CE 649635 Annex II.4	10/05/2023 26/05/2024	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
Sterile lead introducer set peel-away Sterile hemostasis valve introducer kit	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021)
"Extra Safe" dilator sheaths	CE 01906 Annex II.3 CE 720326Annex II.4	10/05/2023 26/05/2024	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)

FIAB SpA – 50039 Vicchio - Firenze - Italia
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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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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**

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

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

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

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EU Quality Management System Certificate

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

MDR 747884 R000

Certificate History

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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Vicchio (FI), 12th January 2023

To whom it may concern

AUTHORIZATION LETTER

"We, manufacturing company FIAB SpA, with headquarters at Via P. Costoli, 4 – 50039 Vicchio (FI) Italy , hereby confirm that we have authorized the company Labromed Laborator SRL (fiscal code 1012600001177) with registered office at Str. Cuza Voda 30/1, Chisinau, MD2060, Moldova, hereinafter referred to as "Authorized Manufacturer's Representative":

to represent interests of our company in all necessary state bodies and institutions for testing, registration and certification of medical equipment produced by FIAB SpA.

to carry out the discusslons relating to testing and registration of medical equipment produced by FIAB SpA.

to submit all necessary documents to state bodies and institutions

to introduce amendments and addendum inserts into documents, to give explanations, to submit additional information

to obtain all necessary documents under FIAB SpA name

to receive the Registration Certificates (electronic or hard copies on paper) under FIAB SpA name

This Agreement is valid until 31/12/2023.

Yours faithfully,

Alberto Calabrò
President of the Board