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

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