DEKRA Certification GmbH – Handwerkstraße 15 – D -70565 Stuttgart

pfm medical titanium gmbh
Frau Britta Tacke
Südwestpark 42
90449 Nürnberg
Deutschland

Handwerkstraße 15
D -70565 Stuttgart

Contact Julia Scheu
Phone +49.711.7861-4158
Fax +49.711.7861-2615
Email julia.scheu@dekra.com

Date 2023-12-18

Subject: Notified Body Confirmation Letter

Our reference: Confirmation Letter 51334-CoL-00, Rev. 00

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 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mrs. Tacke

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 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:

pfm medical titanium gmbh
Südwestpark 42
90449 Nürnberg
Deutschland

SRN Number (if available): DE-MF-000008139

The devices covered by the formal application and the written agreement mentioned above are identified in the Table 1 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 MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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 the Notified Body,

Digitally signed by Stephanie Donner
Date: 2023-12-18 09:04:31+01:00

Stephanie Donner
2023-12-18

Enclosures:

Confirmation Letter Annex – Table 1

Table 1: Devices covered by this letter and for which the notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Product or product group identification acc. to MDD - certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision	MDR Application
Hernia Meshes	Class IIb	Certificate No. 51334-16-02 with Annex Rev. 0, dated 2018-12-17; NB No. 0124	MDR Application ID: A22021369
Pelvic Floor Meshes including Incontinence Meshes	Class IIb	Certificate No. 51334-16-02 with Annex Rev. 0, dated 2018-12-17; NB No. 0124	MDR Application ID: A22021369
Application Set for soft tissue reinforcement implants - TiLOOP® Total Application Set	Class IIa	Certificate No. 51334-16-02 with Annex Rev. 0, dated 2018-12-17; NB No. 0124	for which the replacement product TiLOOP® PLUS Catheter Set has been submitted to DEKRA Certification GmbH MDR Application ID: A23041495