DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

pfm medical mepro gmbh
Herr Horst Gebhard
Am Söterberg 4
66620 Nonnweiler-Otzenhausen
Germany

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Date 2025-01-22

Subject: Notified Body Confirmation Letter

Our reference: 51133-CoL-02 Rev. 1

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 Mr. Gebhard

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 from the following manufacturer for the devices listed in the annex:

pfm medical mepro gmbh
Am Söterberg 4
66620 Nonnweiler-Otzenhausen
Deutschland

SRN Number (if available): DE-MF-000005190

Table 1 identifies the devices for which a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR has been concluded between pfm medical mepro gmbh and DEKRA Certification GmbH and for which DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the DEKRA Certification GmbH has not yet taken the responsibility 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the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).

Confirmation letters no. 51133-CoL-00 Rev.00 is invalid with immediate effect.

Validity of this confirmation letter:

For products included in table 1

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607

On behalf of the Notified Body,

Digitally signed by Markus RAINER Kopf
Date: 2025-02-11 17:39:44+01:00

Markus Kopf
Director Medical Devices

Enclosures:

Confirmation Letter Annex

Table 1

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	Agreement for , Conformity Assessment
Nit-Occlud® PFO	Class III	N/A	Certificate #51133-16-04; NB #0124 Certificate #51133-23-A2; NB #0124	Offer/Order No.: A21111663
Nit-Occlud® PDA	Class III	N/A	Certificate #51133-16-04; NB #0124 Certificate #51133-23-E1; NB #0124	Offer/Order No.: A23091318
ASEPT® Peritoneal Drainage System	Class IIb	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A22081197
ASEPT® Pleural Drainage System	Class IIb	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A22081197
ASEPT® Drainage Line Set	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A22081197
Redon-Drain	Class IIa	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A22051084
Redon-Set	Class IIa	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A22051084
Redon-Bottle	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A22051084
Redon-Connector, Redon-Connection Tube	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A22051084
Multi-Snare®	Class III	N/A	Certificate #51133-16-04; NB #0124	Offer/Order No.: A23091318
Dispo-Flow Drain Product or product group identification acc. to MDD - certificate: **Drains, Wound**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00

Soft-Drain Product or product group identification acc. to MDD - certificate: **Drains, Wound**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Endo-Drain Product or product group identification acc. to MDD - certificate: **Drains, Wound**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Soft-Drain Flat Single Product or product group identification acc. to MDD - certificate: **Drains, Wound**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Micro Introducer Kit Product or product group identification acc. to MDD - certificate: **Catheter Introducer**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Redon-Mini-Set Product or product group identification acc. to MDD - certificate: **Wound Drainage Kits**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Low Vacuum System Product or product group identification acc. to MDD - certificate: **Wound Drainage Kits**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00

Soft Super Plus System Product or product group identification acc. to MDD - certificate: **Wound Drainage Kits**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Soft-Drain Flat System Product or product group identification acc. to MDD - certificate: **Wound Drainage Kits**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Soft-Drain Set Product or product group identification acc. to MDD - certificate: **Wound Drainage Kits**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Soft-Drain Flat Active Product or product group identification acc. to MDD - certificate: **Wound Drainage Kits**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
primeMidline Product or product group identification acc. to MDD - certificate: **Catheter, intravenous peripheral**	Class IIa	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00

Biliary Drainage Bag Product or product group identification acc. to MDD - certificate: **Drainage Bags**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Kinder-Urinbeutel Product or product group identification acc. to MDD - certificate: **Urinary Collection Bags, Infant**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Urinary Collection Bag Product or product group identification acc. to MDD - certificate: **Urinary Collection Bags**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Urinbeutel Product or product group identification acc. to MDD - certificate: **Urinary Collection Bags**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Umbilical Cord Clamp Product or product group identification acc. to MDD - certificate: **Clamps, umbilical**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Redon-Mini Suction Bellow Product or product group identification acc. to MDD - certificate: **Reservoir**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00

Soft-Drain Flat Reservoir Product or product group identification acc. to MDD - certificate: **Reservoir**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Koelner Drainage Product or product group identification acc. to MDD - certificate: **Reservoir**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
Inway Plus Urinmesssystem Product or product group identification acc. to MDD - certificate: **Urinary Drainage Units**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
ASEPT® Replacement Valve Product or product group identification acc. to MDD - certificate: **Fittings/Adapters Luer Lock**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00
ASEPT® Drainage Kit L **ASEPT® Drainage Kit** Product or product group identification acc. to MDD - certificate: **ASEPT® Drainage Kit L** **ASEPT® Drainage Kit**	Class I(s)	N/A	Certificate #51133-16-04; NB #0124	51133-CA-00