EU Certificate

for the assessment of the quality management system



according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the manufacturer

pfm medical mepro gmbh

Single Registration Number (SRN): DE-MF-000005190
Am Söterberg 4, 66620 Nonnweiler-Otzenhausen, Germany

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo51133-01 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51133-60-03-01

Certificate valid from: 2025-11-09
Certificate valid to: 2030-11-08

Previous certificate no. 51133-60-03-00, issued on 2025-07-17

Digitally signed by Markus RAINER Kopf
Date: 2025-08-26 16:15:31+02:00

Markus Kopf
DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

Annex to the EU Certificate no. 51133-60-03-01

Following devices/device categories are included in this certificate:

Class Is

For the devices listed below, the review of the quality management system refers exclusively to the aspects relating to establishing, securing and maintaining sterile conditions.

MDN 1202

- Redon-Bottle, Basic UDI-DI 4042301A0603ADHJ
- Redon-Connector, Redon-Connection Tube, Basic UDI-DI 4042301A0701AAHD
- NeoBreathe, Basic UDI-DI 4042301R0280AASA
- ASEPT® Drainage Line Set, Basic-UDI-DI 4042301A0680AAJM

Class IIa

MDN 1202

- Administration Set LL 2012, Basic UDI-DI 4042301A0304AAGG
- Administration Set APL 2002, Basic UDI-DI 4042301A0304AAGG
- JetCan Pro Safety Huber Needle, Basic-UDI-DI 4042301A0101ACFF
- Redon-Set, Basic UDI-DI 4042301A0601AGHE
- Redon-Drain, Basic UDI-DI 4042301A0601ABH4

Class IIb

MDN 1104

- ASEPT® Peritoneal Catheter, Basic-UDI-DI: 4042301A0602AAH7
- ASEPT® Pleural Catheter, Basic-UDI-DI: 4042301A0602ABH9

Intended Use:

The ASEPT® Peritoneal Catheter is a tunneled catheter that is suitable for short-term and long-term use. It is intended for access of the peritoneal cavity and drainage of accumulated fluid from the abdomen to relieve symptoms such as dyspnea.

The ASEPT® Pleural Catheter is a tunneled catheter that is suitable for short-term and long-term use. It is intended for access of the pleural cavity and drainage of accumulated fluid from the pleural cavity to alleviate the symptoms of pleural effusion.

For the initial placing on the market of class IIb implantable devices covered by this certificate, an EU technical documentation assessment certificate according to Regulation (EU) 2017/745 Annex IX Chapter II is required.

Class III

MDN 1101

- Nit-Occlud Lê VSD, Basic-UDI-DI 4042301P0704ABRV

For the initial placing on the market of class III devices covered by this certificate, an EU technical documentation assessment certificate according to Regulation (EU) 2017/745 Annex IX Chapter II is required.

Changes to previous certificate: Addition of new device ASEPT® Drainage Line Set