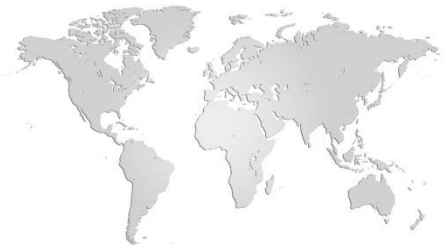
EU Certificate

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 CNo51133-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51133-60-02-00

Certificate valid from: 2023-12-15
Certificate valid to: 2025-11-08

Previous certificate no. 51133-60-01, issued on 2023-09-06

Digitally signed by Stephanie Donner
Date: 2023-12-15 12:31:41+01:00

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

DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Annex to the EU Certificate no. 51133-60-02-00

Following devices/device categories are included in this certificate:

Class IIa

Name of the device/ device category:

Basis-UDI-DI 4042301A0304AAGG

- Administration Set APL 2002,
- Administration Set LL 2012

Basis-UDI-DI 4042301A0101ACFF

- JetCan Pro Safety Huber Needle

Class III

Name of the device/ device category:

Nit-Occlud® Lê VSD, Basis-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.

Change to previous certificate: Addition of a new device