

CERTIFICATE

Number: 2234683

The management system of the organization(s) and locations mentioned on the addendum belonging to:

PFM Medical, Inc.

1916 Palomar Oaks Way, Suite 150
Carlsbad, CA 92008
United States of America

Manufacturer Facility Identifier F003461

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

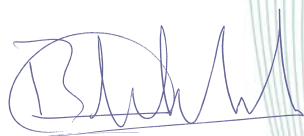
Scope:

Design and development, manufacture and distribution of drainage catheters, peritoneal dialysis catheters, peripherally inserted central catheters, implanted port and catheter systems, percutaneous retrieval devices, vascular occlusion devices, drainage collection devices, needle infusion sets, IV sets, Surgical Masks, surgical mesh, intravascular catheters, surgical instruments, and procedure packs/kits for the areas of cardiovascular, and general surgery and hospital use.

Certificate expiry date: 2028-02-01
Certificate effective date: 2025-02-01
Certified since: 2019-02-20

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed.

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-checkme.com/org>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2234683

The management system of the organization(s) and/or location(s) of:

PFM Medical, Inc.

1916 Palomar Oaks Way, Suite 150
Carlsbad, CA 92008
United States of America

Certified organization(s) and/or locations:

Different scope

PFM Medical, Inc.
1916 Palomar Oaks Way, Suite 100
Carlsbad, CA 92008
United States Of America
Facility Identifier F003461

Warehousing of raw materials and finished goods for the areas of cardiovascular, and general surgery and hospital use.

Addendum expiry date: 2028-02-01
Addendum effective date: 2025-02-01