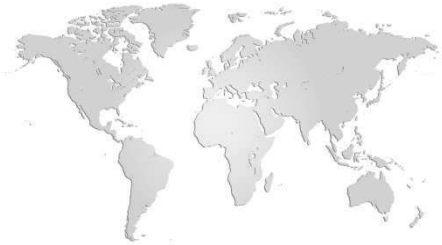
EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

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

pfm medical cpp S.A.

9, Allée du Quartz, 2300 La Chaux-de-Fonds, Switzerland

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51502-Z1-00, the decision dated 2021-01-08 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2021-01-08 to 2024-03-21

Registration No.: 51502-16-00

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2021-01-08
Notified Body ID-number: 0124

Annex to the EC Certificate No. 51502-16-00

Valid from 2021-01-08 to 2024-03-21

Revision status of the annex: 0 dated 2021-01-08

Devices/device categories included in the certificate:

Class III:

- Implantable Vascular Access Ports and Accessories

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-01-08
Notified Body ID-number: 0124