Certificate

EC Design Examination
Annex II.4 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that a design examination has been carried out on the device(s) listed in annex I to this certificate following the requirements of annex II.4 of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

pfm medical ag

Wankelstr. 60, 50996 Köln, Germany

ECM certifies that the design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.4 of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.

Report Number	Registered under	Valid until
014-13BFA7	Z/17/04109E	August 13th, 2022

Aachen, August 14th, 2017

Certification Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-240.10.12

Annex I of Certificate Z/17/04109E

Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Nonactive implantable products	Embolization Prostheses, Intravascular Nit-Occlud® PDA 143106; 143126: 143146; 145044; 145054; 145065; 145076; 145096; 145116	15-034

Special terms of validity:

None.

[1] UMDNS Code ist optional