# Certificate

## Full Quality Assurance System Approval
Annex II excluding (4) of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (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 full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

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 quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

| Audit Report Number | Registered under | Valid until |
|---|---|---|
| 014-17-420 | Z/17/04108E | 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/17/04108E


ecm
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 |
|---|---|---|
| single use devices | Embolization Prostheses, Intravascular | 15-034 |

Special terms of validity:

None.

UMDS Code is optional