

# 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, D-50996 Köln

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.

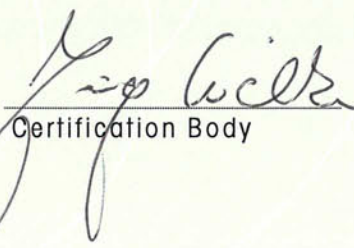
Any substantial changes of the examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.

Report Number  
014-22E821

Registered under  
Z/10/02199

Valid until  
July 22<sup>nd</sup>, 2015

Aachen, July 22<sup>nd</sup>, 2010

  
Certification Body



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZE-985.94.07



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

# Annex I of Certificate Z/10/02199

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Date of revision: September 24<sup>th</sup>, 2010



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code <sup>1</sup>
Nonactive implantable products	Embolization Prostheses, Intravascular	15-034
	Nit-Occlud <sup>®</sup> PFO	
	182020, size 20mm	
	182026, size 26mm	
Nonactive implantable products	Embolization Prostheses, Intravascular	15-034
	Nit-Occlud <sup>®</sup> Lê VSD	
	149086, 8x6, 6F	
	149106, 10x6, 6F	
	149126, 12x6, 6F	
	149148, 14x8, 7F	
149168, 16x8, 7F		

Special terms of validity:

None.

<sup>1</sup> UMDNS Code ist optional