

# 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

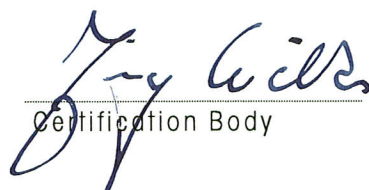
ECM certifies that the design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.4 of the Directive 93/42/EEC on medical devices.

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
014-09C732	Z/15/03627E	July 22 <sup>nd</sup> , 2020

Aachen, July 23<sup>rd</sup>, 2015

  
Certification Body



# Annex I of Certificate Z/15/03627E

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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 <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	182030, size 30mm	15-034
	Embolization Prostheses, Intravascular	
	Nit-Occlud <sup>®</sup> Lê VSD	
	149086, 8x6, 6F	
	149106, 10x6, 6F	
	149126, 12x6, 6F	
	149128, 12x8, 7F	
	149148, 14x8, 7F	
149168, 16x8, 7F		

Special terms of validity:

None.

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