

EC Design- Examination Certificate



**according to directive 93/42/EEC,
annex II (4)**

As a notified body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

pfm medical mepro gmbh

Am Söterberg 4, 66620 Nonnweiler-Otzenhausen, Germany

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC annex II.4 as documented in the report mentioned in the Annex.

Product: Occluder Nit-Occlud Lê VSD

This certificate is valid from 2017-07-02 to 2022-07-01

Certificate registration No.: 51133-23-B2

A handwritten signature in black ink over a circular seal. The seal contains the text 'DEKRA Certification GmbH' at the top, 'DEKRA' in the center, and 'Stuttgart, Handwerkstraße 15' at the bottom.

DEKRA Certification GmbH Stuttgart; 2017-06-28
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten www.zlg.de
ZLG-BS-296.10.01

Annex to the EC design examination certificate 51133-23-B2 2017-06-28

Revision status: 1

Date: 2017-11-30

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Report number: 51133-P2-03 and CN17-01

Product: Occluder Nit-Occlud Lê VSD

Intended use:

The product Nit-Occlud Lê VSD is intended for closure of VSD heart defects (Ventricular Septal Defect).

Technical data:

Ref-No.	Size
149086	8x6mm
149106	10x6mm
149126	12x6mm
149128	12x8mm
149148	14x8mm
149168	16x8mm

