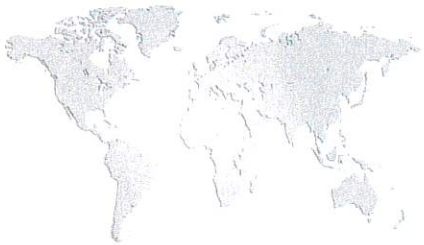
# EC Design Examination Certificate



## according the 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: **Nit-Occlud PDA**

This certificate is valid from 2019-11-12 to 2024-05-26

Registration No.: 51133-23-E1

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-11-11
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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# Annex to the EC Design Examination Certificate No. 51133-23-E1

Revision status: 1

Valid from 2020-04-21 to 2024-05-26

Report number: 51133-P5-04

Product: Nit-Occlud PDA

Intended use:

The Nit-Occlud® PDA coil for PDA Occlusion is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of patent ductus arteriosus.

Technical data:

| REF | Diameter of the coil | Implantation Catheter | Length of the Implantation Catheter | Length of the coil | Type |
|---|---|---|---|---|---|
| 145044 V1 | 4 x 4 mm | 4 F | 85 cm | 3,5 mm | Flex |
| 145054 V1 | 5 x 4 mm | 4 F | 85 cm | 3,5 mm | Flex |
| 145065 V1 | 6 x 5 mm | 4 F | 85 cm | 3,5 mm | Flex |
| 145076 V1 | 7 x 6 mm | 5 F | 85 cm | 4,5 mm | Medium |
| 145096 V1 | 9 x 6 mm | 5 F | 85 cm | 5,0 mm | Medium |
| 145116 V1 | 11 x 6 mm | 5 F | 85 cm | 6,0 mm | Medium |

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