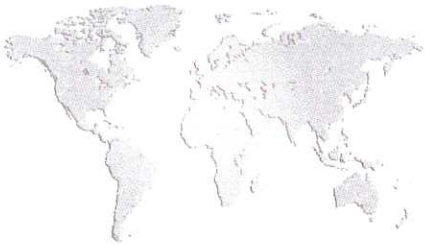
EC Design-Examination Certificate



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: Nit-Occlud PDA-R

This certificate is valid from 2017-08-28 to 2022-07-01

Certificate registration No.: 51133-23-C2

DEKRA Certification GmbH Stuttgart; 2017-08-28
Notified Body ID-number: 0124

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

84460

Annex to the EC design examination certificate 51133-23-C2 dated 2017-08-28

DEKRA Certification GmbH • D-70565 Stuttgart Handwerkstraße 15

Report number: 51133-P3-02

Product: Nit-Occlud PDA-R

Intended use:

The Nit-Occlud PDA-R is an implant developed for the transcatheter closure of the Patent Ductus Arteriosus (PDA)

Technical data:

Ref-No.	Stent (mm)	Disc (mm)	Length (mm)
160102	4	8	6,5
160103	5,5	10	7
160104	7	12	8,5
160105	8,5	14	9,5
160106	10	16	11
160107	11,5	18	12
160108	13	20	13,5
160112	4 - 5	7	5
160113	5 - 6	9	5
160114	6 - 8	11	6
160115	8 - 10	13	7
160116	9 - 11	15	8
160117	11 - 13	17	10
160118	12 - 14	19	11
160119	13 - 16	21	11
160120	15 - 18	23	11