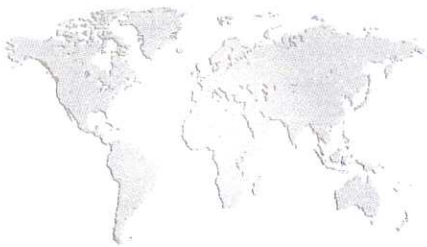
EC Design-Examination Certificate



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 ASD-R

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

Certificate registration No.: 51133-23-D3

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

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Annex to the EC design examination certificate 51133-23-D3 dated 2017-08-28

Revision status: 0 Date: 2017-08-28

Report number: 51133-P4-02

Product: Nit-Occlud ASD-R

Intended use:

The Nit-Occlud® ASD-R is an implant device developed for the transcatheter closure of ostium secundum atrial septal defects (CIA II or ASD II).

Technical data:

Ref-No.	Stent (mm)	Disc (mm)	Rim (mm)
160208	8	16	4.0
160210	10	19	4.5
160212	12	22	5.0
160214	14	24	5.0
160216	16	28	6.0
160218	18	30	6.0
160220	20	33	6.5
160222	22	35	6.5
160224	24	38	7.0
160226	26	42	8.0
160228	28	44	8.0
160230	30	47	8.5