

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

Occlutech Tıbbi Ürünler San. Ve Tic. Ltd. Şti.

Yeşilköy SB Mah., E Blok Sok. Occlutech Apt. No:6, 34149 Bakırköy / İstanbul, Turkey

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: Occlutech® PDA Occluder

This certificate is valid from 2021-03-26 to 2024-05-26

Registration No.: 51322-23-A3


Ruth Delbeck-Bayer



DEKRA Certification GmbH Stuttgart; 2021-03-26
Notified Body ID-number: 0124



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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Annex to the EC Design Examination Certificate No. 51322-23-A3

Revision status: 0

Valid from 2021-03-26 to 2024-05-26

Report number: 51322-P1-05, 51322-CN20-05

Product: Occlutech® PDA Occluder

Intended use: The Occlutech® Patent Ductus Arteriosus (PDA) Occluder is an occlusion system, which is percutaneously implanted through a catheter intervention technique and intended for the non-surgical occlusion of Patent Ductus Arteriosus (PDA).

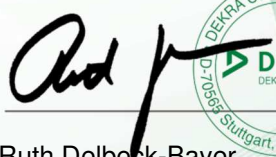
Technical data:

Standard PDA:

Occlutech PDA Occluder Ref. No	Ø D1 Disc Diameter [mm]	Ø D2 Waist Diameter [mm]	Ø D3 Shank Diameter [mm]	Length L Device Length [mm]
42PDA05	9	3.5	5	4.25
42PDA06	10	4	6	5.00
42PDA07	11	5	7	6.05
42PDA08	13	6	8	6.30
42PDA10	16	8	10	7.00
42PDA12	18	10	12	12.00
42PDA15	20	12	15	14.00
42PDA18	24	14	18	16.00

PDA with long shank:

Occlutech PDA Occluder Ref. No	Ø D1 Disc Diameter [mm]	Ø D2 Waist Diameter [mm]	Ø D3 Shank Diameter [mm]	Length L Device Length [mm]
43PDA05L	9	3.5	5	7.00
43PDA06L	10	4	6	7.50
43PDA07L	11	5	7	8.50
43PDA08L	13	6	8	9.00
43PDA10L	16	8	10	10.50





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