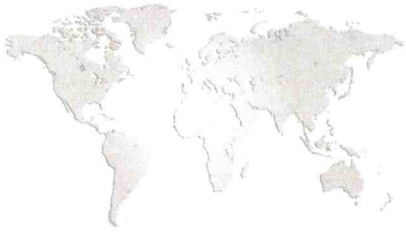
EC Design Examination Certificate



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 GmbH

Winzerlaer Straße 2, 07745 Jena, 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: Figulla® Flex II UNI

This certificate is valid from 2018-10-01 to 2022-02-14

Registration No.: 51030-23-E3

DEKRA Certification GmbH * D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-09-17
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Design Examination Certificate No. 51030-23-E3

Revision status: 0

Valid from 2018-10-01 to 2022-02-14

Report number: 51030-P5-02, 51030-CN18-02

Product: Figulla® Flex II Uni

Intended use: The Occluder Figulla® Flex II Uni are designed for closure of close fenestrated (multifenestrated) atrial septal defects.

Technical data:

Article-No.	Diameter disc [mm]
16UNI17	17
16UNI24	24
16UNI28	28.5
16UNI33	33
16UNI40	40

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