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 ASD Occluder

This certificate is valid from 2021-05-20 to 2024-05-26

Registration No.: 51030-23-D4

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2021-05-20
Notified Body ID-number: 0124

Annex to the EC Design Examination Certificate No. 51030-23-D4

Revision status: 0

Valid from 2021-05-20 to 2024-05-26

Report number: 51030-P4-07

Product: Figulla® Flex II ASD Occluder

Intended use: The Figulla Flex II ASD is a permanent cardiac implant intended to be delivered by a percutaneous, transcatheter procedure and to close atrial septal defects of type ostium secundum

Technical data:

	Article-No. Figulla® Flex II ASD	Diameter waist [mm]
	29ASD04	4
	29ASD05	5
	29ASD06	6
	29ASD07	7,5
	29ASD09	9
	29ASD10	10,5
	29ASD12	12
	29ASD13	13,5
	29ASD15	15
	29ASD16	16,5
	29ASD18	18
	29ASD19	19,5
	29ASD21	21
	29ASD24	24
	29ASD27	27
	29ASD30	30
	29ASD33	33
	29ASD36	36
	29ASD39	39
	29ASD40	40

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