



CERTIFICATE

EC Certificate No. 1434-MDD-178/2021

EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

Eclipse Medical Co., Ltd.

**88/62 Moo 1, 345 Road
Bangtanai, Pakkret
Nonthaburi, 11120 Thailand**

related to the medical device, class III

OMEGA LAA Occluder

The list of medical devices covered by this certificate is provided in the annex 1

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 16.04.2021 to 27.05.2024

The date of issue of the Certificate: 16.04.2021

The date of the first issue of the Certificate: 03.08.2020



Issued under the Contract No. MD-59/2020
Application No. 054/2021
Certificate bears the qualified signature.
Warsaw, 16.04.2021
Module H1

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.04.16
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ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No. 1434-MDD-178/2021

List of medical devices covered by the certificate:

OMEGA LAA Occluder				
Model	Device Size	Cup Diameter	Disc Diameter	Device Length
OLAA14	14 mm	14 mm	23 mm	10 mm
OLAA16	16 mm	16 mm	25 mm	10 mm
OLAA18	18 mm	18 mm	27 mm	10 mm
OLAA20	20 mm	20 mm	29 mm	10 mm
OLAA22	22 mm	22 mm	31 mm	10 mm
OLAA24	24 mm	24 mm	33 mm	15 mm
OLAA26	26 mm	26 mm	35 mm	15 mm
OLAA28	28 mm	28 mm	37 mm	15 mm
OLAA30	30 mm	30 mm	39 mm	15 mm

OMEGA LAA Deliver System				
Model	Sheath size	Dilator size	Loader size	Delivery Cable
OLAA14F	14F	14F	14F	6F



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Warsaw, 16.04.2021

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