



ECLIPSE
MEDICAL

DECLARATION OF CONFORMITY
(Directive 93/42/EEC)

Document: EM-DOC-01

Revision: 03

Product: LAA occluders and delivery systems

Effective date: 01-Jan-22

Manufacturer: Eclipse Medical Co., Ltd.
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Nonthaburi 11120, Thailand
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MALTA

Declaration:
The manufacturer, Eclipse Medical Co., Ltd. exclusively responsible for this declaration of conformity, declares that the products listed hereafter meet the applicable provisions of the European Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states. All supporting documentation is retained under the premises of the manufacturer.

	LAA Occluders	LAA Occluder Delivery Systems
UMDNS Code	17731	10658
GMDN Code	45418	45419
Classification	Class III according to rule 8	Class III according to rule 6

Intended Use The OMEGA LAA Occluder is a permanent implant to close a Left Atrial Appendage by percutaneous insertion.

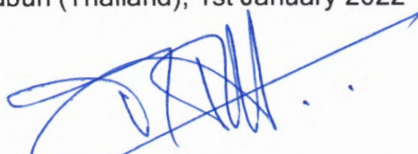
Conformity assessment route: EC Declaration of Conformity in accordance with Annex II of the Medical Device Directive

Notified body: Polish Center for Testing and Certification
469 Pulawska Street,
02-844 Warsaw, Poland



EC-Certificate: 1434-MDD-179/2021 (EC Certificate - Full Quality Assurance System)
1434-MDD-178/2021 (EC Design Examination Certificate)

Place and date of issue: Nonthaburi (Thailand), 1st January 2022


Kasiraman Mayuram Jayaraman
Managing Director

Eclipse Medical Co., Ltd.
บริษัท อีคลิพส์ เมดิคอล จำกัด



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Appendix I - Product Listing/Schedule

Model	Description	UDI-DI
OLAA14	OMEGA LAA Occluder 14 mm	08857127156026
OLAA16	OMEGA LAA Occluder 16 mm	08857127156033
OLAA18	OMEGA LAA Occluder 18 mm	08857127156040
OLAA20	OMEGA LAA Occluder 20 mm	08857127156057
OLAA22	OMEGA LAA Occluder 22 mm	08857127156064
OLAA24	OMEGA LAA Occluder 24 mm	08857127156071
OLAA26	OMEGA LAA Occluder 26 mm	08857127156088
OLAA28	OMEGA LAA Occluder 28 mm	08857127156095
OLAA30	OMEGA LAA Occluder 30 mm	08857127156101
OLAA14F	OMEGA LAA Delivery System 14F	08857127156132

Appendix II - Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
MDD 93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer



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