elios

BAUSCH + LOMB

Attachment to the

Instructions for use - EN

MLase Item No.: 512293

1025_IFU_ELIOS laser console_UK_Rev A / 2025-12

MLase REF 513193-00

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This "Annex to the Instructions for Use" supplements the Instructions for Use "1025_IFU_ELIOS laser console_EN_Rev D" in the marketing area "United Kingdom".

Additional information:

UK Responsible Person (or UKRP)

MedEnvoy UK Limited

85, Great Portland Street, First Floor

London, W1W 7LT

United Kingdom

7 Declaration of Conformity

MLase	CE Declaration of Conformity	Docu-Identifier 2367_JUR-UK-MDR-DOC_Rev A	
	according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices	Revision A	Page 1/1

Medical Device	ELIOS laser console
Classification	IIb, according to Annex VIII of Regulation (EU) 2017/745.
Basic UDI-DI	426238496_512293_AL
Manufacturer	MLase GmbH Industriestrasse 17 82110 Germering, Germany
Manufacturer SRN	DE-MF-000015881
UK Responsible Person (UKRP)	MedEnvoy UK Limited 85 Great Portland Street First Floor London England, United Kingdom W1W 7LT

We hereby declare that the device identified above complies with all applicable provisions of Regulation (EU) 2017/745. This Declaration of Conformity is issued under our sole responsibility.

Conformity assessment procedure performed	Annex IX Chapter I, Section 2 and 3
Notified Body	TÜV Rheinland LGA Products GmbH, identification number 0197
EC-Certificate	HZ 2551152-1
CE-mark since	since 2025-02-06 according to Regulation (EU) 2017/745
Declaration of Conformity valid until	2030-02-05

Germering, 2025-12-04

Anika Reibenspiess
SME for Regulatory Affairs

Dirk Mühlhoff
Executive Management,

Master for this document: TEMP_2367_JUR-UK-MDR-DOC_Rev A