Notified Body
Identification number

0805

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate Number
MRA Q00068

EC Certificate

Full Quality Assurance Procedures

Annex II, excluding section 4, of the Council Directive 93/42/EEC on Medical Devices

Issued to

Manufacturer Name: Ellex Medical Pty Ltd

Manufacturer Address: 3-4 Second Avenue
MAWSON LAKES SA 5095
Australia

For the Design and Manufacture of device categories listed on page 2 of this certificate.

This is to certify that the Full Quality Assurance System described below conforms to the relevant provisions of Annex II, excluding section 4, of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Full Quality Assurancce System which applies at every stage from design to final controls.

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

Commencement Date: 13 May 2021

Certificate Expiry Date: 16 May 2024

Associated CA Certificate: AU Q00226

This certificate is issued by:

Leila Kalbassi
Signed electronically
Delegate of the Secretary
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

Notified Body Identification number

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MRA Q00068

Scope of Certificate

Manufacturer Facilities

	Name and Address	Scope
1	Ellex Medical Pty Ltd 3-4 Second Avenue MAWSON LAKES SA 5095 Australia	Design, Production, Labeling, Final Release, Warehousing, Dispatch

Design and Manufacture of Device Categories

	Description	Limitations (if applicable)
1	Ophthalmic surgical lasers and accessories	
2	Ophthalmic ultrasound systems	

Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	22 June 2009	2009/001798
1.2	Addition of ophthalmic ultrasound systems	12 October 2011	2011/012449
2.1	Recertification	23 May 2014	2013/024379
2.2	Addition of manufacturing facility at Mawson Lakes Update of scope and address of manufacturing facility at Gilbert Street Update to the certificate version numbers as internal TGA modifications	16 February 2017	2016/029384
2.3	Removal of 'Technology Park' from address for Mawson Lakes manufacturing facility	17 February 2017	2016/029384
2.4	Change scope of Gilbert Street facility to 'Legal Manufacturer Address' only.	08 March 2018	E18-201449
2.5	Change in manufacturer's legal address from 82 Gilbert Street, Adelaide SA 5000 to 3-4 Second Avenue, Mawson Lakes, SA 5095 Removal of manufacturer facility at 82 Gilbert Street, Adelaide SA 5000	04 December 2018	E18-334859
3.1	Recertification	16 May 2019	E18-368452
3.2	Re-issued certificate to include ink signature	28 June 2019	2010/010869
3.3	Expansion of indications for the device Lasers, Ophthalmic, Nd: YAG under the device category Ophthalmic surgical lasers and accessories to include YAG Vitreolysis	28 April 2021	E21-259707
3.4	Amending the certificate for page number correction	13 May 2021	E21-259707
Certificate Location (Manufacturer Root File Number):			2010/010652