CE DECLARATION OF CONFORMITY

MANUFACTURER	Ellex Medical Pty Ltd 3-4 Second Avenue Mawson Lakes, South Australia 5095 AUSTRALIA
EUROPEAN AUTHORISED REPRESENTATIVE	M Devices Group / EC Rep Ltd Healthcare Education Centre, Portland St Southport PR8 1HU United Kingdom
In accordance with the following Directives:	**93/42/EEC Medical Device Directives (MDD)** **2011/65/EU Restriction of Hazardous Substances (RoHS 2)**
hereby declare that:	
PRODUCT	Ellex tango™ Ophthalmic Laser and Accessories
MODEL No. and COMMENCING SERIAL No.	**Model:** LT5106-T, **Comm S/N:** TG1100
MDD CLASSIFICATION	IIb, Rule 9
MDD CONFORMITY ASSESSMENT ROUTE	Annex II.3
RoHS 2 EXEMPTIONS	2011/65/EU Annex III 6(c) and 13(b)
CE Mark	First Applied: 21 April 2005
NOTIFIED BODY	Therapeutic Goods Administration (0805)
EC CERTIFICATE	EC Certificate No: MRA Q00068 Valid Until: 16 May 2024
QUALITY MANAGEMENT SYSTEM	ISO 13485:2016
QMS CERTIFICATES	Certificate No: FM701539 (BSI) Valid Until: 14 March 2022 Certificate No: MDSAP 699104 (BSI) Valid Until: 14 March 2023
STANDARDS APPLIED	See Attached Schedule
AUTHORISED SIGNATORY	**Jack Verbeek** Quality & Regulatory Affairs Manager
DATE OF DECLARATION	22 June 2020

Schedule of Standards Applied

Ellex Medical Pty Ltd declare under our sole responsibility that the product listed in this Declaration of Conformity is in compliance with the following standards and other normative documents.

Standard ID	Title	Edition/Date
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	2016
EN ISO 14971	Medical devices – Application of risk management to medical devices	2019
IEC 60601-1	Medical electrical equipment – Part 1: General requirements	2005 (3rd Ed) + CORR 1. 2006 and CORR 2. 2007 + A1:2012
IEC 60601-1-2	Medical electrical equipment – Part 1-2: Electromagnetic compatibility	2014 (4th Ed)
IEC60601-1-6	Medical electrical equipment – Part 1-6: Collateral Standard: Usability	2010 (3rd Ed) + A1:2013
IEC 60601-1-8	Medical electrical equipment – Part 1-8: Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	2006 (2nd Ed) + A1:2012
IEC 60601-2-22	Medical electrical equipment – Part 2-22: particular requirements for the safety of diagnostic and therapeutic laser equipment	2007 (3rd Ed) + A1: 2012
IEC 60825-1	Safety of laser products – Part 1: Equipment classification, requirements and user's guide	2014 (3rd Ed)
IEC 62304	Medical devices software – Software life cycle processes	2006
BS EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	2016
BS EN 1041	Information supplied by the manufacturer of medical devices	2008 + A1:2013