

CERTIFICATE OF REGISTRATION

N° 34436-0

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LNE certifies that the quality management system developed by

New World Medical, Inc.

10763 Edison Court,

RANCHO CUCAMONGA, CA 91730 UNITED STATES

D.U.N.S. identification number :62-276-8711

for the activities

Conception, fabrication et distribution de valves à glaucome et d'instruments de chirurgie ophtalmique

Design, manufacture, and distribution of glaucoma valves and ophthalmic surgical instruments

performed on the location(s) of

Voir addendum/See addendum: 2 sites/ New World Medical - USA

**has been audited and found to conform to the requirements of the international standard
ISO 13485 : 2003 and following regulatory requirements**

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japon	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité / Effective date : June 26th, 2018 (included)

Valable jusqu'au / Expiry date : February 28th, 2019 (included)

Etabli le / Issued on : June 26th, 2018



LNE is authorised under the Medical Devices Single Audit Program
This certificate is issued according to the rules of G-MED Certification
The validity of this certificate can be verified on www.gmed.fr



On behalf of the G-MED Certification Director

Béatrice L...

G-MED Certification Technical Director

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

French version:

Conception, fabrication et distribution de valves à glaucome et d'instruments de chirurgie ophtalmique

English version:

Design, manufacture, and distribution of glaucoma valves and ophthalmic surgical instruments

✚ **New World Medical - 10763 Edison Court, Rancho Cucamonga, CA 91730 USA**
Headquarters and Manufacturing

✚ **New World Medical - 10743 Edison Court, Rancho Cucamonga, CA 91730 USA**
Design, Engineering (Research and development), Inspection and post marketing activities

2 sites / 2 sites



On behalf of the Certification Director
Béatrice LYS
G-MED Certification Technical Director