

GMED certifies that the quality management system developed by

New World Medical, Inc.

**10763 Edison Court,
RANCHO CUCAMONGA, CA 91730 UNITED STATES**

Facility identifier (REPs-generated) : F000712

for the activities

Conception, fabrication et distribution de dispositif de drainage de glaucome et d'instruments chirurgicaux dans le domaine de l'ophtalmologie

Design, manufacture, and distribution of glaucoma shunts and surgical instruments for the area of ophthalmology.

performed on the location(s) of

**10763 Edison Court Rancho Cucamonga, CA 91730 USA
10743 Edison Court Rancho Cucamonga, CA 91730 USA
10783 Edison Court Rancho Cucamonga, CA 91730 USA**

**has been audited and found to conform to the requirements of the international standard
ISO 13485 : 2016 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. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	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 December 23rd, 2022 (included)

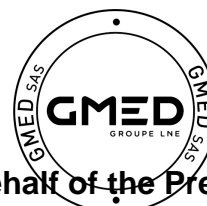
Valable jusqu'au / Expiry date : June 25th, 2024 (included)

Etabli le / Issued on : December 23rd, 2022



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

Modifie le certificat 35370-2



DocuSigned by:

Béatrice LYS
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**On behalf of the President
Béatrice LYS
Technical Director**

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

New World Medical, Inc.
10763 Edison Court
Rancho Cucamonga, CA 91730 - USA

Siège social et Fabrication
Headquarters and Manufacturing

New World Medical, Inc.
10743 Edison Court
Rancho Cucamonga, CA 91730 - USA

Conception, ingénieries (recherche et développement), inspection et activités de post-commercialisation
Design, Engineering (Research and development), Inspection and post marketing activities

New World Medical, Inc.
10783 Edison Court
Rancho Cucamonga, CA 91730 – USA

Gestion, marketing, ressources humaines, fabrication et control
Management, marketing, human resources, manufacturing, and inspection

3 sites / 3 sites



DocuSigned by:

Béatrice LYS

EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director