

GMED certifies that the quality management system developed by

ECA Medical Instruments

1107 Tourmaline Drive

NEWBURY PARK, CA 91320 UNITED STATES

Facility identifier (REPs-generated) : F002858

for the activities

Conception et fabrication d'instruments à usage unique stériles ou non stériles comprenant: limiteurs de couple brevetés et instruments chirurgicaux destinés à la chirurgie de management du rythme cardiaque, de neuromodulation, cardiovasculaire et orthopédique

Design and manufacture of single use proprietary torque-limiting devices and surgical instruments supplied sterile or non-sterile and intended to be used for cardiac rhythm management (CRM), neuromodulation, cardiovascular, and orthopedic surgeries

performed on the location(s) of

ECA Medical Instruments 1107 Tourmaline Drive Newbury Park, CA 91320 USA

ECA Medical Instruments 2193 Anchor Court Thousand Oaks, CA 91320 USA

ECA Medical Instruments 2192 Anchor Court, Suite B Thousand Oaks, CA 91320 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
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité / Effective date February 8th, 2025 (included)

Valable jusqu'au / Expiry date : February 7th, 2028 (included)

Etabli le / Issued on : January 20th, 2025



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

Renouvelle le certificat 35300-3

DocuSigned by:
Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director



GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Ce certificat couvre les activités et les sites suivants:

This certificate covers the following activities and sites:

ECA Medical Instruments

1107 Tourmaline Drive
Newbury Park, CA 91320 - USA

Moulage par injection, usinage sur machine à commande numérique, ébavurage, lavage,
assemblage, contrôle qualité, et livraison / *Injection molding, CNC machining, tumbling,*
washing, assembly, QC Inspection and shipping

ECA Medical Instruments

2193 Anchor Court
Thousand Oaks, CA 91320 - USA

Conception et moulage par injection / *Design and injection molding*

ECA Medical Instruments

2192 Anchor Court, Suite B
Thousand Oaks, CA 91320 - USA

Conception / *Design*

3 sites / **3 sites**

DocuSigned by:
Béatrice LYS
EF33BDA9BAA04A3...



On behalf of the President
Béatrice LYS
Technical Director