

Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by

ECA Medical Instruments
1107 Tourmaline Drive
NEWBURY PARK, CA 91320 UNITED STATES

pour les activités
for the activities

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

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

réalisées sur le(s) site(s) de
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

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485:2003

Début de validité / Effective date March 17th, 2016 (included)

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

Etabli le / Issued on : March 16th, 2016



On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

LNE N° 26873-2

LNE: CMDCAS recognized registrar / This certificate is issued according to the rules of G-MED certification and CMDCAS program requirements / CMDCAS SQ

Renouvelle le certificat 26873-1

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

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

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

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

French version: Moulage par injection, usinage sur machine à commande numérique, ébavurage, lavage, assemblage, contrôle qualité, et livraison

English version: Injection molding, CNC machining, tumbling, washing, assembly, QC Inspection and shipping

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

French version: Conception, moulage par injection et usinage sur machine à commande numérique

English version: Design, injection molding and CNC machining

2 sites / 2 sites



On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager