

GMED certifies that the quality management system developed by

Epitope Diagnostics, Inc.

17034 Camino San Bernardo,

San Diego, California 92127 UNITED STATES

Facility identifier (REPs-generated) : F008878

for the activities

**Conception, développement, fabrication et distribution de dispositifs de diagnostic in vitro,
notamment des réactifs d'immunoanalyse, des kits de test
(voir champ de certification complet dans l'addendum)**

*Design, development, manufacture, and distribution of in vitro diagnostic devices, including immunoassay
reagents, testing kits
(see full scope in the addendum)*

performed on the location(s) of

Epitope Diagnostics, Inc. 17034 Camino San Bernardo, San Diego, California 92127 USA

**has been audited and found to conform to the requirements of the international standard
ISO 13485 : 2016 and following regulatory requirements**

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 July 27th, 2026 (included)

Valable jusqu'au / Expiry date : July 26th, 2029 (included)

Etabli le / Issued on : July 27th, 2026



GMED is recognised 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.lne-gmed.com.



Signé par :



EF33BDA9BAA04A3...

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:

Epitope Diagnostics, Inc.

**17034 Camino San Bernardo,
San Diego, California 92127
USA**

Conception, développement, fabrication et distribution de dispositifs de diagnostic in vitro, notamment des réactifs d'immunoanalyse, des kits de test pour la détection des affections gastro-intestinales, du cancer, des marqueurs cardiaques, des marqueurs de la reproduction et des stéroïdes, des marqueurs du diabète et de l'obésité, des troubles du métabolisme osseux, du statut auto-immun et de l'anémie.

Design, development, manufacture, and distribution of in vitro diagnostic devices, including immunoassay reagents, testing kits for detecting gastrointestinal conditions, cancer, cardiac markers, reproductive and steroid markers, diabetes and obesity markers, bone metabolism disorders, autoimmune status, and anemia.

1 site / 1 site

Signé par : 
EF33BDA9BAA04A3...

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