

CERTIFICATE OF REGISTRATION N° 39177–2

page 1 of 1

GMED certifies that the quality management system developed by

Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA 19355 UNITED STATES

Facility identifier (REPs-generated): F006507

for the activities

Conception et fabrication de tests de marqueurs tumoraux de diagnostic in vitro pour la surveillance de maladies spécifiques.

Design and Manufacture of In Vitro Diagnostic Tumour Marker Tests for the Monitoring of Specific Disease Conditions.

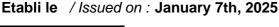
performed on the location(s) of

201 Great Valley Parkway Malvern PA 19355 USA 3119 Phoenixville Pike Malvern, PA 19355 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 807Subparts A to D

Début de validité / Effective date February 6th, 2025 (included) Valable jusqu'au / Expiry date : February 5th, 2028 (included)





On behalf of the President

Béatrice LYS

Technical Director

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 39177-1

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



Addendum au certificat n° 39177 rev. 2 page 1/1 Addendum of the certificate n° 39177 rev. 2 Dossier / File N°T002108 P1-R

Ce certificat couvre les activités et les sites suivants:

This certificate covers the following activities and site:

Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA 19355 USA

Conception et Production / Design and Production

REPs #: F006507

Warehouse

3119 Phoenixville Pike Malvern, PA 19355 USA **Stockage** / Storage

2 sites / 2 sites



On behalf of the President Béatrice LYS Technical Director