CERTIFICATE OF REGISTRATION

N° 39177–0

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) : F003527

for the activities

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

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

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* **November 1st, 2022 (included)**
Valable jusqu'au */ Expiry date :* **February 5th, 2025 (included)**
Etabli le */ Issued on :* **November 1st, 2022**

DocuSigned by: Béatrice LYS EF33BDA9BAA0443...

GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

GMED_MDSAP2016-F-V0-07-