

*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<br>RDC ANVISA n. 551/2021<br>RDC ANVISA n. 67/2009  |
| Canada        | Medical Devices Regulations - Part 1 - SOR 98/282  |
| United States | 21 CFR 820<br>21 CFR 803<br>21 CFR 806<br>21 CFR 807 - -Subparts A to D  |

**Début de validité / Effective date February 6th, 2025 (included)**

**Valable jusqu'au / Expiry date : February 5th, 2028 (included)**

**Etabli le / Issued on : January 7th, 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](http://www.gmed.fr)

Renouvelle le certificat 39177-1



DocuSigned by:

*Béatrice LYS*  
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**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 site:*

**Fujirebio Diagnostics, Inc.**

201 Great Valley Parkway

Malvern, PA 19355 USA

**Conception et Production / Design and Production**

**REPs #: F006507**

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**Warehouse**

3119 Phoenixville Pike

Malvern, PA 19355 USA

**Stockage / Storage**

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**2 sites / 2 sites**



DocuSigned by:

*Béatrice LYS*

EF33BDA9BAA04A3...

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