

*GMED certifies that the quality management system developed by*

**FUJIREBIO EUROPE N.V.**

**Technologiepark 6,  
9052 GENT BELGIUM**

**Facility identifier (REPs-generated) : F004207**

*for the activities*

**Conception et développement, fabrication, installation et maintenance de dispositifs médicaux de diagnostic in vitro utilisés dans le diagnostic, la gestion, la détection d'analytes dans les domaines pathologiques. Voir addendum.**

*Design and development, manufacturing, installation and servicing of in-vitro diagnostic medical devices used in diagnosis, management, detection of analytes in the disease fields . See addendum.*

*performed on the location(s) of*

**FUJIREBIO EUROPE N.V. Technologiepark 6, 9052 GENT BEL**

**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
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

**Début de validité / Effective date December 14th, 2024 (included)**

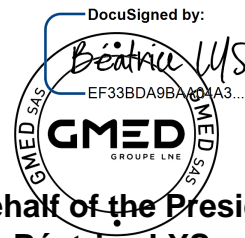
**Valable jusqu'au / Expiry date :December 13th, 2027 (included)**

**Etabli le / Issued on : December 6th, 2024**



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 35087-2



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

**Ce certificat couvre les activités et le site suivant :**

*This certificate covers the following activities and site:*

**FUJIREBIO EUROPE N.V.**  
**Technologiepark 6**  
**9052 GENT**  
**BELGIUM**


**French version:**

Conception et développement, fabrication, installation et maintenance de dispositifs médicaux de diagnostic in vitro utilisés dans le diagnostic, la gestion, la détection de l'état auto-immun, analytes sanguins, analytes du liquide céphalo-rachidien, composants sanguins, neurodégénérescence, cancer, test de compatibilité, état de la maladie, dépistage des donneurs, tests génétiques, état immunitaire, dépistage prénatal, agents sexuellement transmissibles, typage tissulaire, agents transmissibles et typage immunologique.

**English version:**

*Design and development, manufacturing, installation and servicing of in-vitro diagnostic medical devices used in diagnosis, management, detection of autoimmune status, blood analytes, cerebrospinal fluid analytes, blood components, neurodegeneration, cancer, compatibility testing, disease status, donor screening, genetic testing, immune status, prenatal screening, sexually transmissible agents, tissue typing, transmissible agents and immunological typing.*

**1 site / 1 site**

DocuSigned by:  
*Béatrice LYS*  
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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**