CERTIFICATE OF REGISTRATION

N° 35087–2

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* **February 9th, 2023 (included)**
Valable jusqu'au */ Expiry date :* **December 13th, 2024 (included)**
Etabli le */ Issued on :* **February 9th, 2023**

DocuSigned by:
MARJORIE PERRIMON
761B7BDEC7B144D...

On behalf of the President
Marjorie PERRIMON
Certification 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

Modifie le certificat 35087-1

GMED_MDSAP2016-F-V0-07-

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:
MARJORIE PERRIMON
761B7BDE...B144D...

On behalf of the President
Marjorie PERRIMON
Certification Director