CERTIFICATE OF REGISTRATION

N° 35087–0

GMED certifies that the quality management system developed by

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

D.U.N.S. identification number : 29-734-6645

for the activities

Conception, développement, fabrication, distribution, installation et prestations associées pour les dispositifs médicaux de diagnostic in vitro pour les catégories : INNO-LIA, INNO-LiPA, INNOTEST associés aux instruments et logiciels dédiés.

Design, development, manufacturing, distribution, installation & servicing of in vitro diagnostic medical devices for the product categories INNO-LIA, INNO-LiPA, INNOTEST & related instruments & software.

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. 16/2013 RDC ANVISA n. 23/2012 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, 2018 (included)**
Valable jusqu'au / *Expiry date* :**December 13th, 2021 (included)**
Etabli le / *Issued on* : **December 14th, 2018**

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 SAS GMED GROUPE LNE GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

GMED_MDSAP2016-F-V0-07-