CERTIFICATE OF REGISTRATION

N° 35058–1

GMED certifies that the quality management system developed by

BIO-RAD

3 boulevard Raymond Poincaré

92430 MARNES-LA-COQUETTE FRANCE

Facility identifier (REPs-generated) : F004054

for the activities

Conception/développement, production et fabrication sous contrat de kits de diagnostic in vitro, de réactifs, d'instruments et de logiciels de diagnostic in vitro. Voir addendum

The design/development, production and contract manufacturing of in-vitro diagnostic test kits, reagents, instruments and software. See addendum

performed on the location(s) of

MARNES-LA-COQUETTE - ROANNE - STEENVOORDE - SCHILTIGHEIM - FRA

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 12th, 2021 (included)**

Valable jusqu'au / *Expiry date :* **December 11th, 2024 (included)**

Etabli le / *Issued on :* **December 1st, 2021**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA...

On behalf of the President

Béatrice LYS

Technical Director

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

Renouvelle le certificat 35058-0

GMED_MDSAP2016-F-V0-07-

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

French Version :
Conception/développement, production et fabrication sous contrat de kits de diagnostic in vitro, de réactifs, d'instruments et de logiciels de diagnostic in vitro utilisés pour le diagnostic des maladies causées par des agents infectieux transmissibles et sexuellement transmissibles, l'étude de la sensibilité des micro-organismes aux agents antimicrobiens, le diagnostic et le suivi des maladies immunes et auto-immunes et en Immuno-Hématologie.
English Version:
The design/development, production and contract manufacturing of in-vitro diagnostic test kits, reagents, instruments and software used in the diagnosis of diseases caused by infectious agents transmissible and sexually transmissible, the determination of microbial susceptibility to antibiotics, the diagnosis and monitoring of immune and auto-immune disorders and in Immuno-Hematology testing.

Concerne les sites et les activités suivants:

1) **BIO-RAD - 3 Bd Raymond Poincaré - 92430 MARNES-LA-COQUETTE - FRANCE**
Conception / développement ; *Design / development*
2) **BIO-RAD - Route de Cassel - 59114 STEENVOORDE - FRANCE**
Conception / développement, production ; *Design / development, production*
3) **BIO-RAD - 7 rue de Madrid - 67300 SCHILTIGHEIM - FRANCE**
Conception / développement, production ; *Design / development, production*
4) **BIO-RAD - 18 avenue du Polygone - 42300 ROANNE - FRANCE**
Conception / développement, production ; *Design / development, production*

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4 sites / *4 sites*

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