CERTIFICATE OF REGISTRATION

N° 35146–2

GMED certifies that the quality management system developed by

Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Drive,
HERCULES, CA 94547 UNITED STATES

Facility identifier (REPs-generated) : F001526

for the activities

Conception et développement, fabrication et distribution de kits de tests de diagnostic in vitro, d'analyseurs et de logiciels de diagnostic in vitro. Voir addendum.

Design and development, manufacture and distribution of in-vitro diagnostic test kits, in-vitro diagnostic analyzer and software. See addendum.

performed on the location(s) of

See addendum

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* **March 7th, 2022 (included)**
Valable jusqu'au / *Expiry date :* **December 20th, 2024 (included)**
Etabli le / *Issued on :* **March 7th, 2022**

DocuSigned by:
Béatrice Lys
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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

Modifie le certificat 35146-1

GMED_MDSAP2016-F-V0-07-2018

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

French version:
Conception et développement, fabrication et distribution de kits de tests de diagnostic in vitro, d'analyseurs et de logiciels de diagnostic in vitro utilisés pour la sérologie et la chimie, le diagnostic des maladies causées par des agents transmissibles et des agents sexuellement transmissibles et le diagnostic et/ou le suivi des désordres endocriniens et métaboliques, des maladies auto-immunes, des troubles génétiques et pour la toxicologie, incluant l'abus de drogue.

English version:
Design and development, manufacture and distribution of in-vitro diagnostic test kits, in-vitro diagnostic analyzers and software used for serology and special chemistry, diagnosis of diseases caused by transmissible agents and sexually transmissible agents and diagnosis and/or monitoring of hemoglobin variants, diabetes, autoimmune diseases, genetic disorders and toxicology, including drug of abuse.

- **Bio-Rad Laboratories, Inc. - 4000 Alfred Nobel Drive, Hercules, CA 94547, USA**
  Administration, recherche et développement, fabrication et entreposage.
  Administration, research and development, manufacturing and warehousing.

- **Bio-Rad Laboratories, Inc. - 800 Alfred Nobel Drive, Hercules, CA 94547, USA**
  Conditionnement de produits finis.
  Packaging of finished goods.

- **Bio-Rad Laboratories, Inc. - 5500 East Second Street, Benicia, CA 94510, USA**
  Conception et développement.
  Design and development.

- **Bio-Rad Laboratories (Singapore) Pte Ltd. - 1 kaki Bukit View #03-01 - 415941 Techview - Republic of Singapore**
  Fabrication.
  Manufacturing.

4 sites / *4 sites*

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