

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

Design and development, manufacture, distribution and services 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. 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 21st, 2024 (included)

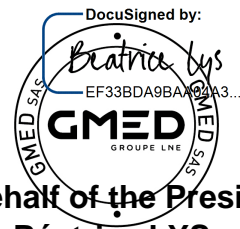
Valable jusqu'au / Expiry date :December 20th, 2024 (included)

Etabli le / Issued on : February 21st, 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

Modifie le certificat 35146-3



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

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

French version :

Conception et développement, fabrication, distribution et services de kits de tests de diagnostic in vitro, d'analyseurs et de logiciels de diagnostic in vitro utilisés pour le dépistage des donneurs, les tests sérologiques et les diagnostics liés aux maladies causées par des agents transmissibles et des agents sexuellement transmissibles, le diagnostic et/ou le suivi des variants de l'hémoglobine, du diabète, des troubles endocriniens, des maladies immunitaires et auto-immunes, des troubles génétiques, de la toxicologie, incluant l'abus de drogue.


Fabrication et distribution d'instruments et de kits de PCR digitale utilisés pour le suivi du cancer.

English version:

Design and development, manufacturing, distribution and service of in vitro diagnostic test kits, analysers and software used for donor screening, serological testing and diagnosis related to diseases caused by transmissible agents and sexually transmissible agents, diagnosis and/or monitoring of haemoglobin variants, diabetes, endocrine disorders, immune and autoimmune disorders, genetic disorders, toxicology, including drugs of abuse. Manufacturing and distribution of digital polymerase chain reaction (PCR) instruments and kits used for monitoring of cancer.

- **Bio-Rad Laboratories, Inc. - 4000 Alfred Nobel Drive, Hercules, CA 94547, USA.**
Administration, fabrication et entreposage / Administration, 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. - 725 Alfred Nobel Drive, Hercules, CA 94547, USA .**
Conception et développement / Design and development.
- **Bio-Rad Laboratories, Inc., 255 Linus Pauling Hercules, CA 94547, USA.**
*Support technique à la clientèle, service sur le terrain et spécialistes en diagnostic.
Technical Customer Support, field service and diagnostic specialist.*
- **Bio-Rad Laboratories, Inc., 265 Linus Pauling Hercules, CA 94547, USA.**
Support produit / Product Support
- **Bio-Rad Laboratories (Singapore) Pte Ltd. - 1 kaki Bukit View #03-01 - 415941 Techview Republic of Singapore**
Fabrication d'instruments / Instrument Manufacturing

6 sites / 6 sites

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