

GMED certifies that the quality management system developed by

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

D.U.N.S. identification number :13 252 8295

for the activities

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

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

performed on the location(s) of

**Bio-Rad Laboratories, Inc. - 4000 Alfred Nobel Drive - HERCULES - CA 94547 - USA
Bio-Rad Laboratories, Inc. - 800 Alfred Nobel Drive - HERCULES - CA 94547 - USA
Bio-Rad Laboratories, Inc. - 5500 East Second Street - BENICIA - CA 94510 - USA**

**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

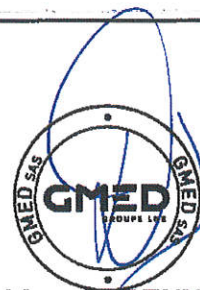
Début de validité / Effective date December 21st, 2018 (included)

Valable jusqu'au / Expiry date :December 20th, 2021 (included)

Etabli le / Issued on : December 21st, 2018



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



**Lionel DREUX
Certification Director**

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 et d'analyseurs/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 and in-vitro diagnostic analyzer / 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**
French version: Administration, recherche et développement, fabrication et entreposage.
English version: Administration, research and development, manufacturing and warehousing.
- ↪ **Bio-Rad Laboratories, Inc. - 800 Alfred Nobel Drive, Hercules, CA 94547, USA**
French version: Conditionnement de produits finis.
English version: Packaging of finished goods.
- ↪ **Bio-Rad Laboratories, Inc. - 5500 East Second Street, Benicia, CA 94510, USA**
French version: Conception et développement.
English version: Design and development.

3 sites / 3 sites



Lionel DREUX
Certification Director