

*GMED certifies that the quality management system developed by*

**Bio-Rad Laboratories Inc.**  
**9500 Jeronimo Road**  
**IRVINE, CA 92618 UNITED STATES**

**D.U.N.S. identification number :05-162-4070**

*for the activities*

**Conception, développement, fabrication, distribution et support technique de dispositifs de diagnostic in-vitro destinés aux programmes de contrôle qualité de laboratoires cliniques**

*Design, development, manufacturing, distribution and technical support of in vitro diagnostic medical devices for clinical laboratory quality control programs*

*performed on the location(s) of*

**Voir addendum/See addendum: 4 sites/ Bio-Rad Laboratories, Inc. - 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
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D 21 CFR 821 (where applicable)

**Début de validité / Effective date November 6th, 2019 (included)**

**Valable jusqu'au / Expiry date :November 27th, 2022 (included)**

**Établi le / Issued on : November 6th, 2019**



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](http://www.gmed.fr)

Renouvelle le certificat 34629-0



**Lionel DREUX**  
Certification Director

**Ce certificat couvre les activités et les sites suivants**  
**This certificate covers the following activities and sites**

**Bio-Rad Laboratories Inc.**  
9500 Jeronimo Road, Irvine, CA 92618 - USA  
Conception, développement, fabrication et support technique  
*Design, development, manufacturing and technical support*

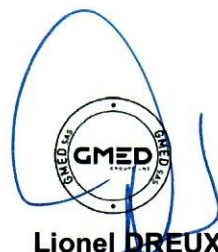
**Bio-Rad Laboratories, Inc.**  
9 Holland Drive, Irvine, CA 92618 - USA  
Distribution / *Distribution*

**Bio-Rad Laboratories, Inc.**  
21 Technology Drive, Irvine, CA 92618 – USA  
Assurance qualité / Affaires réglementaires et services techniques  
*QA/RA and Technical Services*

**Bio-Rad Laboratories Inc.**  
9500 Jeronimo Road, Irvine, CA 92618 - USA  
Matière première et contrôle  
*Raw material and incoming inspection*

\*\*\*\*\*

4 sites

  
**Lionel DREUX**  
Certification Director