

GMED certifies that the quality management system developed by

Bio-Rad Laboratories Inc.

9500 Jeronimo Road

IRVINE, CA 92618 UNITED STATES

Facility identifier (REPs-generated) : F002873

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 May 18th, 2022 (included)

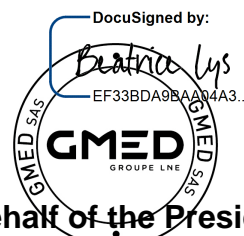
Valable jusqu'au / Expiry date : May 17th, 2025 (included)

Etabli le / Issued on : May 18th, 2022



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 34629-2



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

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.

9560 Jeronimo Road, Irvine, CA 92618 - USA
Matière première et contrôle
Raw material and incoming inspection

4 sites

DocuSigned by:

Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director