CERTIFICATE OF REGISTRATION

N° 34629–6

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: 5 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. 665/2022 RDC ANVISA n. 551/2021 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

Début de validité / *Effective date* **August 6th, 2026 (included)**
Valable jusqu'au / *Expiry date :* **May 17th, 2028 (included)**
Etabli le / *Issued on :* **August 6th, 2026**

Signed by:
A1D80E08C60D47A...
GMED SAS GMED SAS GMED GROUPE LNE

Lionel DREUX
President

MDSAP Medical Device Single Audit Program

GMED is recognised 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.lne-gmed.com.

Modifie le certificat 34629-5

720 GMED 0901-8 rev 2 du 12/DEC/2025

Addendum au certificat n° 34629-6 page 1/1
Addendum of the certificate n° **34629-6**
Dossier / *File* N°P608178

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.
9400 Jeronimo Road Irvine, CA 92618 - USA
Stockage Matières Premières et contrôles d'entrée Assurance qualité, services techniques, commercialisation Raw
Material Warehouse and incoming controls, RA/QA, technical services, marketing

Bio-Rad Laboratories Inc.
9560 Jeronimo Road, Irvine, CA 92618 - USA
Fabrication
Manufacturing

Bio-Rad Laboratories Inc.
100 South Jones Street#100, Fort Worth TX 76104, USA
Conception, développement, fabrication,
Design, development and manufacturing

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5 sites

Signed by:
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Lionel DREUX
President