CERTIFICATE OF REGISTRATION

N° 35906–2

GMED certifies that the quality management system developed by

Bio-Rad Laboratories, Inc.
5731 W. Las Positas Blvd
PLEASANTON, CA 94588 UNITED STATES

Facility identifier (REPs-generated) : F004121

for the activities

Conception et développement, fabrication et distribution de systèmes digitaux de réaction de polymérisation en chaine (PCR) utilisés pour le management des marqueurs résiduels de cancers, et le management du statut de maladie.

Design and development, manufacture and distribution of digital polymerase chain reaction (PCR) systems used for the management of residual cancer markers, and management of disease status.

performed on the location(s) of

Bio-Rad Laboratories, Inc. 5731 W. Las Positas Blvd Pleasanton, CA 94588 - USA
Bio-Rad Laboratories, Inc. 5667 Gibraltar Drive, Pleasanton, CA 94588 - 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
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité / *Effective date* **July 30th, 2022 (included)**
Valable jusqu'au / *Expiry date :* **August 11th, 2025 (included)**
Etabli le / *Issued on :* **July 30th, 2022**

GMED SAS GMED GROUPE LNE GMED SAS

DocuSigned by:
MARJORIE PERRIMON
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On behalf of the President
Marjorie PERRIMON
Certification Director

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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 35906-1

GMED_MDSAP2016-F-V0-07-