CERTIFICATE OF REGISTRATION

N° 34438–3

GMED certifies that the quality management system developed by

BIO-RAD LABORATORIES, Inc.

6565 185th Avenue NE

REDMOND, WA - 98052 UNITED STATES

Facility identifier (REPs-generated) : F000710

for the activities

Conception & développement, fabrication & distribution de DM DIV dont trousses d'essais et réactifs utilisés pour la sélection des donneurs, le diagnostic des agents transmissibles, le diagnostic et le contrôle des troubles endocriniens, immunitaires et autoimmunitaires - Voir add.

Design & development, manufacture & distribution of IVD test kits and IVD reagents used in donor screening, the diagnosis of diseases caused by transmissible agents and the monitoring/diagnosis of endocrine disorders, immune and autoimmune disorders - See add.

performed on the location(s) of

6565 185th Avenue NE - WA 98052 - Redmond - USA
14620 NE N WOODINVILLE Way - Suite 200 - WA 98072-8440 WOODINVILLE - USA
8415 216th, Street SE - WA 98072 WOODINVILLE - 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* **July 18th, 2022 (included)**
Valable jusqu'au */ Expiry date :* **July 17th, 2025 (included)**
Etabli le */ Issued on :* **July 11th, 2022**

DocuSigned by:
Beatrice Lys
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GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical 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 34438-2

GMED_MDSAP2016-F-V0-07-

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

BIO-RAD LABORATORIES, Inc.
6565 185th Avenue NE – Redmond – WA 98052 – USA

French version :
Conception et développement, fabrication et distribution de dispositifs médicaux de diagnostic in vitro dont trousses d'essais et réactifs utilisés pour la sélection des donneurs, le diagnostic des agents transmissibles et sexuellement transmissibles, le diagnostic et le contrôle des troubles endocriniens, des troubles immunitaires et autoimmunitaires.

English version:
Design and development, manufacture and distribution of, in-vitro diagnostic test kits and in-vitro diagnostic reagents used in donor screening, the diagnosis of diseases caused by transmissible agents and sexually transmissible agents and the monitoring/diagnosis of endocrine disorders, immune and autoimmune disorders.

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- **Bio-Rad Laboratories, Inc. – Seattle Operations**
  6565 185th Avenue NE – REDMOND - WA 98052, USA
  Siège Social, Responsable de la mise sur le marché / *Headquarter, Legal manufacturer*

- **Bio-Rad Laboratories, Inc.– Seattle Operations**
  14620 NE N Woodinville Way – Suite 200 – WOODINVILLE, WA 98072-8440, USA
  Fabrication /*Manufacturing*

- **Bio-Rad Laboratories, Inc. – Seattle Operations**
  8415 216th Street SE – WOODINVILLE, WA 98072, USA
  Entrepôt/*Warehouse*

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3 sites / *3 sites*

DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director