GMED
GROUPE LNE

CERTIFICATE OF REGISTRATION

N° 35121–0

GMED certifies that the quality management system developed by

bioMérieux, Inc.
100 Rodolphe Street
Durham, North Carolina 27712 UNITED STATES

D.U.N.S. identification number :086785110

for the activities

Conception, fabrication, distribution et service de dispositifs médicaux de diagnostic in vitro, de trousses d'analyse, de réactifs et d'analyseurs / logiciels utilisés dans le diagnostic et / ou la gestion de la maladie et de l'état bactériologique du patient

Design, manufacture, distribution and service of in vitro diagnostic medical devices, test kits, reagents, and analyzers/software used in the diagnosis and/or management of patient disease and bacteriological status.

performed on the location(s) of

voir addendmum / see addendum - 5 sites 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* **December 18th, 2018 (included)**
Valable jusqu'au / *Expiry date* **:December 17th, 2021 (included)**
Etabli le / *Issued on* **: December 18th, 2018**

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

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On behalf of the President
Béatrice LYS
Technical Director

M.S.D.N:0106034369-C.T.T.N.H.H CÔNG TY TNHH BIOMERIEUX VIỆT NAM QUẬN ĐỐNG ĐA - T.P HÀ NỘI

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Addendum au certificat n° 35121 rev. 0 page 1/1
Addendum of the certificate n° 35121rev. 0
Dossier / *File* N° T000278-2-I

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

bioMérieux, Inc. (Rodolphe)

100 Rodolphe Street, Durham, NC, 27712 USA

Conception, fabrication, distribution et service
Design, manufacture, distribution and service

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bioMérieux (Hamlin Road)

1101 Hamlin Road, Durham, NC 27712 USA

Ventes / traitement des commandes, service client incluant la gestion des réclamations, le marketing, le service d'entretien / formation client
Sales / order processing, customer support including complaint management, marketing, field service / customer training

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bioMérieux (Anglum Road)

595 Anglum Road, Hazelwood, MO 63042 USA

Conception, fabrication, distribution et service
Design, manufacturing, distribution and service

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bioMérieux (Anglum Court)

603 Anglum Court, Hazelwood, MO 63042 USA

Fabrication et remise à neuf d'instruments, stockage et expédition
Instrument manufacturing and refurbishment, storage and shipping

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bioMérieux (Campus Parkway)

5690 Campus Parkway, Hazelwood, MO 63042 USA

Stockage et expédition
Storage and shipping

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5 sites / *5 sites*

On behalf of the President
Béatrice LYS
Technical Director