

GMED certifies that the quality management system developed by

bioMérieux, Inc.

100 Rodolphe Street

Durham, North Carolina 27712 UNITED STATES

Facility identifier (REPs-generated) : F002901

for the activities

Conception et développement, fabrication, distribution et service après-vente de dispositifs médicaux de diagnostic in vitro, kits pour test, réactifs, et analyseurs/logiciels utilisés dans le diagnostic et/ou la gestion de la maladie et du statut bactériologique du patient

Design and development, 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 addendum / see addendum - 6 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, 2021 (included)

Valable jusqu'au / Expiry date : December 17th, 2024 (included)

Etabli le / Issued on : December 2nd, 2021



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 35121-1



**On behalf of the President
Béatrice LYS
Technical Director**

DocuSigned by:

Béatrice Lys
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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, stockage et entretien / Design, manufacture, distribution, storage and servicing

bioMérieux (Hamlin Road)

1101 Hamlin Road, Durham, NC 27704 USA

Traitement de commandes, service client incluant la gestion des réclamations, le service d'entretien sur le terrain / formation client

Order processing, customer support including complaint management, field service / customer training

bioMérieux (Anglum Road)

595 Anglum Road, Hazelwood, MO 63042 USA

Conception et fabrication / Design and manufacture

bioMérieux (Anglum Court)

5603 Anglum Court, Hazelwood, MO 63042 USA

Fabrication, remise à neuf, entretien, stockage et expédition / Manufacture, refurbishment, servicing, storage and shipping

bioMérieux (Campus Parkway)

5690 Campus Parkway, Hazelwood, MO 63042 USA

Conception, stockage, distribution et expédition / Design, storage, distribution, and shipping

bioMérieux (Anglum Court)

5600 Anglum Court, Suite A, Hazelwood, MO 63042 USA

Stockage / Storage

6 sites / 6 sites



DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director