

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, installation 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, installation and servicing 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

See addendum

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
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 1st, 2025 (included)

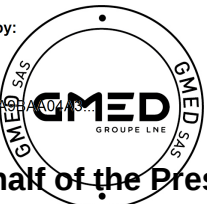
Valable jusqu'au / Expiry date : December 17th, 2027 (included)

Etabli le / Issued on : July 1st, 2025



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.gmed.fr

Modifie le certificat 35121-5

Signed by: 
EF33BD9B1A04634

On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

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
REPS Number: F002901

Conception, fabrication, distribution et stockage / Design, manufacture, distribution and storage

bioMérieux, Inc. (Morrisville)

3015 Carrington Mill Blvd., Suite 200, Morrisville, NC 27560, USA
REPS Number: F002901

Traitement des commandes, service client incluant la gestion des réclamations, le service d'entretien / formation client /
Order processing, customer support including complaint management, field service / customer training

bioMérieux, Inc. (Anglum Road)

595 Anglum Road, Hazelwood, MO 63042 USA
REPS Number: F003509

Conception, fabrication, remise à neuf, entretien, stockage, distribution et expédition /
Design, manufacture, refurbishment, servicing, storage, distribution, and shipping

bioMérieux, Inc. (Salt Lake City)

1201 S 4800 W Salt Lake City, UT 84104 USA
REPS Number: F006391

Traitement de commandes et service client / Order processing and customer support

4 sites / 4 sites

Signed by:

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On behalf of the President
Béatrice LYS
Technical Director