

*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 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*

*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 December 18th, 2024 (included)**

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

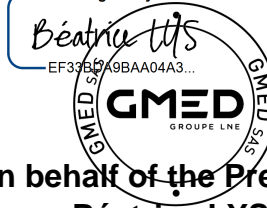
**Etabli le / Issued on : November 20th, 2024**



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](http://www.gmed.fr)

Renouvelle le certificat 35121-4

DocuSigned by:



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

**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**

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**bioMérieux, Inc. (Hamlin Road)**

1101 Hamlin Road, Durham, NC 27704 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*

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**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*

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**bioMérieux, Inc. (Salt Lake City)**

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

**Traitement de commandes / Order processing**

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**4 sites / 4 sites**

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