

Certificat/Certificate: N° 39423 rev. 3

Délivré le /Issued on: April 9th, 2026

Certificat délivré à /Certificate issued to: **bioMérieux, Inc.**

100 Rodolphe Street

Durham, North Carolina 27712 UNITED STATES

SRN: US-MF-000011802

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité et le(s) rapport(s) d'évaluation de la documentation technique associé(s), le cas échéant, référencé(s) T002185 & T002030, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/746 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) and the associated technical documentation assessment report, where appropriate, referenced T002185 & T002030, the quality management system complies with the relevant provisions of the regulation (EU) 2017/746 for the following products:

Dispositifs de diagnostic in vitro: Réactifs et logiciel destinés à être utilisé pour la culture, l'isolement et l'identification d'agents infectieux

In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de diagnostic in vitro de classe D, de diagnostics compagnons de classe C et de dispositifs de diagnostic in vitro d'autodiagnostic et de diagnostic près du patient de classe B et C, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis. La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

For the purpose of placing on the market class D in vitro diagnostic devices, class C companion diagnostics and class B and C in vitro diagnostic devices for self-testing and near-patient testing, another certificate issued in accordance with the provisions of Regulation (EU) 2017/746 is required. The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

Début de validité /Effective date: April 9th, 2026 (included)

Valable jusqu'au /Expiry date: March 28th, 2027 (included)



On behalf of the President
Béatrice LYS
Technical Director

1. Le cas échéant, le nom et l'adresse du mandataire / If applicable, the name and address of the authorised representative:



bioMérieux SA - 376 Chemin de l'orme, 69280 Marcy l'Etoile, France
 SRN: FR-AR-000004435

2. Identification des sites / Identification of sites:

bioMérieux, Inc. - 100 Rodolphe Street, Durham, NC 27712, USA
 bioMérieux, Inc. - 3015 Carrington Mill Blvd., Suite 200, Morrisville, NC 27560, USA
 bioMérieux, Inc. - 595 Anglum Road, Hazelwood, MO 63042, USA
 bioMérieux, Inc. - 1201 S 4800 W Salt Lake City, UT 84104, USA

3. Identification des dispositifs / Identification of devices:

Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents.	VITEK® 2 VIRTUAL, KB UPDATE, V2S 9.04 (424110)	B	The VITEK® 2 System software are intended for the automated quantitative or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp., and clinically significant yeast. The VITEK® 2 Systems software are also intended for the automated identification of most clinically significant anaerobic organisms and Corynebacterium species, fermenting and non-fermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.	N/A

Signé par : 
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On behalf of the President
Béatrice LYS
Technical Director

Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK Systems Software v10.0 (423737)	B	The VITEK® 2 System software are intended for the automated quantitative or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp., and clinically significant yeast. The VITEK® 2 Systems software are also intended for the automated identification of most clinically significant anaerobic organisms and Corynebacterium species, fermenting and non-fermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.	N/A
Reagents and software intended to be used to grow, isolate and identify infectious agents	VIRTUAL, KB UPDATE, V2S 10.1 (424731)	B	The VITEK® 2 Systems product line is intended for the automated quantitative or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp., and clinically significant yeast. The VITEK® 2 System product line is also intended for the automated identification of most clinically significant anaerobic organisms and Corynebacterium species, fermenting and nonfermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.	N/A
Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK 2 SOFTWARE 11.0 (424901)	B	The VITEK® 2 Systems product line is intended for the automated quantitative or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp., and clinically significant yeast. The VITEK® 2 System product line is also intended for the automated	N/A

Signé par :

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On behalf of the President
Béatrice LYS
Technical Director

Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
	(Continued)		identification of most clinically significant anaerobic organisms and Corynebacterium species, fermenting and nonfermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.	

*mentionnée par le fabricant dans la notice d'utilisation / *as included by the manufacturer in the instructions for use*

4. Historique du certificat / Certificate history:

Version du certificat <i>Version of the certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
39423 rev. 0	16/10/2023 <i>10/16/2023</i>	NA : création <i>NA: creation</i>
39423 rev. 1	16/02/2024 <i>02/16/2024</i>	Extension de la liste des dispositifs couverts par le certificat N° 39423 rev. 0 <i>Extension of the list of devices covered by the certificate N° 39423 rev. 0</i>
39423 rev. 2	01/07/2025 <i>07/01/ 2025</i>	Mise à jour de l'adresse (retrait du site "1101 Hamlin Road", ajout du site "3015 Carrington Mill Blvd") <i>Address update (removed site at "1101 Hamlin Road", added site at "3015 Carrington Mill Blvd")</i>
39423 rev. 3	09/04/2026 <i>04/09/2026</i>	<p>Ajout des appareils suivants à la liste des références : VIRTUAL, KB UPDATE, V2S 10.1 et VITEK 2 SOFTWARE 11.0 (ref. T002462_P5 REA) <i>Addition of the following devices to the list of references: VIRTUAL, KB UPDATE, V2S 10.1 and VITEK 2 SOFTWARE 11.0 (ref. T002462_P5 REA)</i></p> <p>Nouvelle référence de dossier pour alignement sur le cycle d'audit actuel <i>New file reference to align with the current audit cycle</i></p> <p>Correction du retrait involontaire du appareils « VITEK® 2 VIRTUAL, KB UPDATE, V2S 9.04 (424110) » <i>Correcting the unintentional removal of the device "VITEK® 2 VIRTUAL, KB UPDATE, V2S 9.04 (424110)"</i></p> <p>Ajout de la référence du dossier technique (ref. T002030) <i>Addition of technical file reference (ref. T002030)</i></p>

5. Le cas échéant, les informations spécifiques relatives aux conditions ou limitations de la validité du certificat / If applicable, specific information relating to the conditions for or limitations to the validity of the certificate: N/A

6. Le cas échéant, les informations spécifiques relatives à la surveillance effectuée par l'organisme notifié / If applicable, specific information about the surveillance carried out by the notified body: N/A

Signé par : 
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On behalf of the President
Béatrice LYS
Technical Director