CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE

Règlement (UE) 2017/746, Annexe IX chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/746, Annex IX chapters I and III

Certificat/*Certificate:* N° 39293 rev. 8

Délivré le/*Issued on:* October 27th, 2025

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, 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, 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:* October 27th, 2025 (included)

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

Signé par : EF33BDA9BA...

On behalf of the President
Béatrice LYS
Technical Director

GMED - 39293 rev. 8
Modifie le certificat 39293-7

720 RDM 0701-98 rev 3 du 29/JAN/2024

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 *Generic name related to the device*	Nom commercial du dispositif *Device trade name*	Classe du dispositif *Device classification*	Destination* du dispositif *Intended purpose* of the device*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-GP67 (22226)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-GP68 (22231)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BD...

On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Dénomination générique associé au dispositif *Generic name related to the device*	Nom commercial du dispositif *Device trade name*	Classe du dispositif *Device classification*	Destination* du dispositif *Intended purpose* of the device*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-GP72 (410770)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-GP74 (414971)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-GP75 (415670)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-GP78 (421051)	Class B	The VITEK® 2 Gram Positive Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed in the Product Information manual.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P576 (22216)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P577 (22218)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P580 (22233)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P584 (22252)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P586 (22276)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P589 (22279)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BD[illegible]

On behalf of the President
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Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P592 (22287)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	(VITEK® 2 AST-P595) (22296)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P596 (22297)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P597 (22298)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P600 (22313)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BD[illegible]

On behalf of the President
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Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P601 (22314)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P603 (22320)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P605 (22325)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P606 (22330)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P608 (22336)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BDA9

On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P611 (22358)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P612 (22359)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P613 (410027)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P616 (410223)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P619 (411944)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BDA9

On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P621 (412533)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P623 (412603)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P625 (413727)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P626 (413863)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P627 (414124)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BD...

On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P628 (414534)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P631 (414961)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P634 (415671)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P635 (416911)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P636 (417951)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BD...

On behalf of the President
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Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P637 (418583)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P638 (418423)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P640 (418579)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P641 (418590)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P643 (418671)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BDA9EAA...

On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P644 (418673)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P645 (419602)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P646 (420144)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P647 (420610)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P648 (420857)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
EF33BD[illegible]

On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Dénomination générique associé au dispositif *Generic name related to the device*	Nom commercial du dispositif *Device trade name*	Classe du dispositif *Device classification*	Destination* du dispositif *Intended purpose* of the device*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P649 (420858)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P650 (421296)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P651 (421586)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P652 (421857)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P653 (421858)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P654 (421912)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P655 (421913)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P656 (421829)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P657 (422072)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P658 (423051)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P659 (423050)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P660 (423231)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P661 (423235)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P662 (423439)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P663 (423646)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P664 (424036)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P665 (424064)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P666 (424113)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P667 (424183)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P668 (424184)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

Signé par :
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In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P670 (424856)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P671 (424982)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P672 (425083)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P673 (425082)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents	VITEK® 2 AST-P675 (425300)	Class B	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents when used as instructed.	N/A

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

Signé par :
EF33BDA9EA...

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4. Historique du certificat / *Certificate history:*

Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39293 rev. 0	**23 mai 2023** *May 23 2023*	**Extension de la liste des dispositifs couverts par le certificat N° 38919 rev. 2, et création de trois nouveaux certificats couvrant les dispositifs ajoutés: N° 39290 rev. 0, N° 39291 rev. 0 et N° 39293 rev. 0** / *Extension of the list of devices covered by the certificate N° 38919 rev. 2, and creation of three new certificates covering the added devices: N#39290 rev. 0, N° 39291 rev. 0 and N#39293 rev. 0*
39293 rev. 1	**23 juin 2023** *June 23, 2023*	**Mise à jour de la liste des références** *Update of list of references* **Nouvelle(s) référence(s) de rapport dans le cadre du maintien de la certification** *New file reference(s) in the framework of the maintenance of the certification* **Correction d'un terme dans le scope en francais** *Correction of a word in the French translation of the scope*
39293 rev. 2	**16 octobre 2023** *October 16th, 2023*	**Mise à jour du champ d'application** *Update of scope*
39293 rev. 3	**14 mai 2024** *May 14th, 2024*	**Mise à jour de la liste des références** *Update of list of references*
39293 rev. 4	**21 novembre 2024** *November 21st, 2024*	**Mise à jour de la liste des références** *Update of list of references*
39293 rev. 5	**4 mars 2025** *March 4th, 2025*	**Mise à jour de la liste des références** *Update of list of references*
39293 rev. 6	**1er juillet 2025** *July 1st, 2025*	**Mise à jour de l'adresse (retrait du site "1101 Hamlin Road", ajout du site "3015 Carrington Mill Blvd")** *Address update (removed site at "1101 Hamlin Road", added site at "3015 Carrington Mill Blvd")*
39293 rev. 7	**4 septembre 2025** *September 4th, 2025*	**Ajout de dispositifs suite à l'extension de gamme T002226-P7-REA** *Addition of devices further to the Range Extension T002226-P7-REA*
39293 rev. 8	**27 octobre 2025** *October 27th, 2025*	**Ajout d'un dispositif suite à l'extension de gamme T002393_P5-REA** *Addition of a device following the Range Extension T002393_P5-REA* **Nouvelle référence de rapport dans le cadre du maintien de la certification** *New file reference in the framework of the maintenance of the certification*

Signé par :
EF33BD...

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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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