

Certificat/Certificate: N° 39293 rev. 3

Délivré le /Issued on: May 14th, 2024

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) T001376, 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 T001376, 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: May 14th, 2024 (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.: 1101 Hamlin Road, Durham, NC 27704 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:

Nom commercial <i>Commercial name</i>	Références commerciales <i>Commercial references</i>	Destination <i>Intended use</i>	Classe du DM DIV <i>IVD MD Class</i>	Référence aux autres certificats requis pour la mise sur le marché <i>Reference to other certificates required for placing on the market</i>
VITEK® 2 AST-GP67	22226	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.	Class B	N/A

DocuSigned by:

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On behalf of the President
Béatrice LYS
Technical Director

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VITEK® 2 AST-GP68	22231	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.	Class B	N/A
VITEK® 2 AST-GP72	410770	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.	Class B	N/A
VITEK® 2 AST-GP74	414971	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.	Class B	N/A
VITEK® 2 AST-GP75	415670	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.	Class B	N/A

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VITEK® 2 AST-GP78	421051	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.	Class B	N/A
VITEK® 2 AST-P576	22216	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.	Class B	N/A
VITEK® 2 AST-P577	22218	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.	Class B	N/A
VITEK® 2 AST-P580	22233	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.	Class B	N/A

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VITEK® 2 AST-P584	22252	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.	Class B	N/A
VITEK® 2 AST-P586	22276	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.	Class B	N/A
VITEK® 2 AST-P589	22279	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.	Class B	N/A
VITEK® 2 AST-P592	22287	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.	Class B	N/A

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VITEK® 2 AST-P595	22296	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.	Class B	N/A
VITEK® 2 AST-P596	22297	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.	Class B	N/A
VITEK® 2 AST-P597	22298	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.	Class B	N/A
VITEK® 2 AST-P600	22313	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.	Class B	N/A

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VITEK® 2 AST-P601	22314	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.	Class B	N/A
VITEK® 2 AST-P603	22320	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.	Class B	N/A
VITEK® 2 AST-P605	22325	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.	Class B	N/A
VITEK® 2 AST-P606	22330	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.	Class B	N/A

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VITEK® 2 AST-P608	22336	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.	Class B	N/A
VITEK® 2 AST-P611	22358	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.	Class B	N/A
VITEK® 2 AST-P612	22359	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.	Class B	N/A
VITEK® 2 AST-P613	410027	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.	Class B	N/A

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VITEK® 2 AST-P616	410223	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.	Class B	N/A
VITEK® 2 AST-P619	411944	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.	Class B	N/A
VITEK® 2 AST-P621	412533	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.	Class B	N/A
VITEK® 2 AST-P623	412603	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.	Class B	N/A

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VITEK® 2 AST-P625	413727	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.	Class B	N/A
VITEK® 2 AST-P626	413863	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.	Class B	N/A
VITEK® 2 AST-P627	414124	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.	Class B	N/A
VITEK® 2 AST-P628	414534	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.	Class B	N/A

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VITEK® 2 AST-P631	414961	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.	Class B	N/A
VITEK® 2 AST-P634	415671	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.	Class B	N/A
VITEK® 2 AST-P635	416911	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.	Class B	N/A
VITEK® 2 AST-P636	417951	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.	Class B	N/A

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Technical Director

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VITEK® 2 AST-P637	418583	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.	Class B	N/A
VITEK® 2 AST-P638	418423	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.	Class B	N/A
VITEK® 2 AST-P640	418579	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.	Class B	N/A
VITEK® 2 AST-P641	418590	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.	Class B	N/A

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Technical Director

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VITEK® 2 AST-P643	418671	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.	Class B	N/A
VITEK® 2 AST-P644	418673	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.	Class B	N/A
VITEK® 2 AST-P645	419602	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.	Class B	N/A
VITEK® 2 AST-P646	420144	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.	Class B	N/A

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VITEK® 2 AST-P647	420610	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.	Class B	N/A
VITEK® 2 AST-P648	420857	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.	Class B	N/A
VITEK® 2 AST-P649	420858	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.	Class B	N/A
VITEK® 2 AST-P650	421296	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.	Class B	N/A

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VITEK® 2 AST-P651	421586	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.	Class B	N/A
VITEK® 2 AST-P652	421857	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.	Class B	N/A
VITEK® 2 AST-P653	421858	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.	Class B	N/A
VITEK® 2 AST-P654	421912	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.	Class B	N/A

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VITEK® 2 AST-P655	421913	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.	Class B	N/A
VITEK® 2 AST-P656	421829	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.	Class B	N/A
VITEK® 2 AST-P657	422072	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.	Class B	N/A
VITEK® 2 AST-P658	423051	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.	Class B	N/A

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VITEK® 2 AST-P659	423050	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.	Class B	N/A
VITEK® 2 AST-P660	423231	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.	Class B	N/A
VITEK® 2 AST-P661	423235	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.	Class B	N/A
VITEK® 2 AST-P662	423439	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.	Class B	N/A

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Béatrice LYS
Technical Director

Nom commercial <i>Commercial name</i>	Références commerciales <i>Commercial references</i>	Destination <i>Intended use</i>	Classe du DM DIV <i>IVD MD Class</i>	Référence aux autres certificats requis pour la mise sur le marché <i>Reference to other certificates required for placing on the market</i>
VITEK® 2 AST-P663	423646	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.	Class B	N/A
VITEK® 2 AST-P664	424036	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.	Class B	N/A
VITEK® 2 AST-P665	424064	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.	Class B	N/A
VITEK® 2 AST-P666	424113	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.	Class B	N/A

DocuSigned by:

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On behalf of the President
Béatrice LYS
Technical Director

Nom commercial <i>Commercial name</i>	Références commerciales <i>Commercial references</i>	Destination <i>Intended use</i>	Classe du DM DIV <i>IVD MD Class</i>	Référence aux autres certificats requis pour la mise sur le marché <i>Reference to other certificates required for placing on the market</i>
VITEK® 2 AST-P670	424856	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.	Class B	N/A

4. Historique du certificat / Certificate history:

Référence au certificat précédent <i>Reference to the previous certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
Certificat N° 38919 rev. 2	12 mai 2023 <i>May 12, 2023</i>	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
Certificat N° 39293 rev. 0	23 mai 2023 <i>May 23, 2023</i>	Mise à jour de la liste des références <i>Update of list of references</i> Nouvelle(s) référence(s) de rapport dans le cadre du maintien de la certification <i>New file reference(s) in the framework of the maintenance of the certification</i> Correction d'un terme dans le scope en français <i>Correction of a word in the French translation of the scope</i>

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On behalf of the President
Béatrice LYS
Technical Director

Référence au certificat précédent <i>Reference to the previous certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
Certificat N° 39293 rev. 1	23 juin 2023 <i>June 23, 2023</i>	Mise à jour du champ d'application <i>Update of scope</i>
Certificat N° 39293 rev. 2	16 octobre 2023 <i>October 16th, 2023</i>	Mise à jour de la liste des références <i>Update of list of references</i>

5. **Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat / If applicable, specific information relating to the limitations to the validity of the certificate: *Non Applicable / Not applicable***
6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat / If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate: *Non Applicable / Not applicable***

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On behalf of the President
Béatrice LYS
Technical Director