

Certificat/Certificate: N° 39291 rev. 1

Délivré le /Issued on: June 23rd, 2023

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 sur le(s) rapport(s) d'audit du système de gestion de la qualité 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 contained in the quality management system audit report(s) 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 destinés à être utilisé pour la culture, l'isolement et l'identification d'agents infectieux.

In vitro diagnostic device: Reagents 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 C (près du patient, autodiagnostic ou diagnostic compagnon) et/ou de classe D, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis.

For the purpose of placing on the market class C in vitro diagnostic devices (devices for self-testing, near patient testing or companion diagnostics) and / or class D, another certificate issued in accordance with the provisions of Regulation (EU) 2017/746 is required.

Début de validité /Effective date: June 23rd, 2023 (included)

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

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.

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.



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-GN09	22008	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN13	22095	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli 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-GN16	22139	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN48	412090	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN66	413398	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN67	413399	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN68	413431	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN69	413400	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-GN70	413401	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN72	413403	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN73	413404	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN74	413941	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN75	413432	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN77	413434	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-GN79	413436	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN80	413437	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN81	413438	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN83	413440	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN84	413410	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN86	413942	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-GN93	414985	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN95	421982	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN99	423102	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N101	22257	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N102	22258	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N169	410220	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N193	412604	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N194	412605	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N195	412609	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N196	412860	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N202	412863	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N203	412864	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N204	412865	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N211	413043	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N212	413061	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N214	413064	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N215	413065	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N222	413083	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N223	413110	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N224	413111	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N225	413112	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N227	413144	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N228	413145	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N229	413146	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N231	413115	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N232	413116	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N233	413117	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N234	413119	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N235	413170	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N238	413203	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N239	413204	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N240	413205	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N242	413391	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N243	413392	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N245	413394	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N246	413395	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N248	413397	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N249	413572	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N250	413573	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N255	413724	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N256	413725	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N257	413726	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N263	413755	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N268	413868	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N269	413869	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N270	414162	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N271	414163	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N272	414164	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N274	414310	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N275	414313	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N276	414286	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N278	414288	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N279	414492	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N280	414531	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

DocuSigned by:

 EF33BDA9BA04A3

On behalf of the President
Béatrice LYS
Technical Director

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VITEK® 2 AST-N281	414532	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N283	414536	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N288	414972	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N289	415057	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N290	415058	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N291	415062	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N292	415063	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N300	416241	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N303	416590	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N308	416913	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N309	416914	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N311	416952	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N314	417027	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N315	417426	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N317	417558	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N318	417952	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N320	418204	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N321	418205	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N322	418489	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N327	418515	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N340	419412	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N341	420061	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N344	420440	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N347	420867	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N349	420859	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N351	421257	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N352	421258	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N353	421297	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N356	421352	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N357	421451	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N358	421441	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N359	421573	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N360	421583	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N361	421584	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N362	421585	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N363	421692	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N365	421830	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N366	421853	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N367	421854	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N368	421855	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N369	421856	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N371	422024	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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Technical Director

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VITEK® 2 AST-N372	422241	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N373	423007	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N374	423008	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N375	423098	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N376	423025	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N378	423038	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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Technical Director

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VITEK® 2 AST-N379	423052	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N380	423053	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N381	423054	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N382	423055	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N383	423056	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N384	423101	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N385	423097	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N386	423275	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N387	423313	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N388	423327	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N389	423334	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N390	423340	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N391	423341	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N392	423342	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N395	423491	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N396	423492	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N397	423588	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N398	423591	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N401	423643	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N402	423644	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N403	423645	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N404	423664	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N405	423864	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N408	423924	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N409	423925	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N410	423926	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N411	423927	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N413	423928	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N414	423933	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N415	423934	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-N416	423935	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N417	423880	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N419	423948	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N421	424055	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N422	424056	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N424	424120	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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On behalf of the President
Béatrice LYS
Technical Director

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VITEK® 2 AST-N800	423310	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N801	423416	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-N802	423706	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN04	410401	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN05	413230	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN06	413944	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-XN08	421983	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN09	423425	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN10	423587	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN11	423589	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN12	423590	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN13	423592	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A

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VITEK® 2 AST-XN14	423602	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN15	423829	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN16	423861	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN17	423673	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-XN20	423947	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Class B	N/A
VITEK® 2 AST-GN76	413433	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A

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VITEK® 2 AST-N261	413753	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N293	415369	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N325	418513	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N330	418674	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N331	418675	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A

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VITEK® 2 AST-N332	418676	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N339	419341	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N343	420063	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N346	420597	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N350	421037	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A

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VITEK® 2 AST-N437	424498	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N438	424499	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N439	424501	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N440	424502	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N441	424539	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A

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VITEK® 2 AST-N442	424538	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N443	424541	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N444	424587	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N445	424306	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N446	424599	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A

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VITEK® 2 AST-N447	424620	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-N448	424633	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-XN26	424500	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A
VITEK® 2 AST-XN28	424586	The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic gram negative bacilli to antimicrobial agents when used as instructed in the Product Information manual.	Class B	N/A

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On behalf of the President
Béatrice LYS
Technical Director

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	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
Certificat N° 39291 rev. 0	23 juin 2023 June 23, 2023	<p>Mise à jour de la liste des références <i>Update of list of references</i></p> <p>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</p> <p>Correction d'un terme dans le scope en français Correction of a word in the French translation of the scope</p>

- 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**