

DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

Validity declaration of conformity from date / Date de déclaration de conformité :

Place / Lieu d'émission :

bioMerieux Inc., 100 Rodolphe Street,
Durham, NC, 27712, U.S.A.

Date of the issue of the declaration of conformity /
Date d'application de la déclaration de conformité :

04Apr2022

Name - Title / Nom - Fonction :

DocuSigned by:

Nathan Hardesty – Associate Director,
Regulatory Affairs

Signature :



Signer Name: Nathan Hardesty
Signing Reason: I approve this document
Signing Time: 4/7/2022 | 3:15:31 PM CEST
92ED8F2A8A974D53898FA56CAEAF035

Product identification / Identification du produit :

Name / Nom :

VITEK 2 AST CARDS

AST-XN01 cat# 410025, AST-XN04 cat# 410401, AST-XN05 cat# 413230, AST-XN06 cat# 413944, AST-XN07 cat# 420441, AST-XN08 cat# 421983, AST-XN09 cat# 423425, AST-XN10 cat# 423587, AST-XN11 cat# 423589, AST-XN12 cat# 423590, AST-XN13 cat# 423592, AST-XN14 cat# 423602, AST-XN15 cat# 423829, AST-XN16 cat# 423861, AST-XN17 cat# 423673, AST-XN18 cat# 423874, AST-XN19 cat# 424200, AST-XN20 cat# 423947, AST-XN21 cat# 424197, AST-XN22 cat# 424199, AST-XN23 cat# 424198, AST-XN24 cat# 424351, AST-XN25 cat# 424394, AST-GN04 cat# 22000, AST-GN09 cat# 22008, AST-GN13 cat# 22095, AST-GN14 cat# 22096, AST-GN16 cat# 22139, AST-GN48 cat# 412090, AST-GN66 cat# 413398, AST-GN67 cat# 413399, AST-GN68 cat# 413431, AST-GN69 cat# 413400, AST-GN70 cat# 413401, AST-GN71 cat# 413402, AST-GN72 cat# 413403, AST-GN73 cat# 413404, AST-GN74 cat# 413941, AST-GN75 cat# 413432, AST-GN76 cat# 413433, AST-GN77 cat# 413434, AST-GN79 cat# 413436, AST-GN80 cat# 413437, AST-GN81 cat# 413438, AST-GN82 cat# 413439, AST-GN83 cat# 413440, AST-GN84 cat# 413410, AST-GN86 cat# 413942, AST-GN87 cat# 413943, AST-GN89 cat# 414367, AST-GN90 cat# 414779, AST-GN91 cat# 414780, AST-GN92 cat# 414963, AST-GN93 cat# 414985, AST-GN95 cat# 421982, AST-GN99 cat# 423102, AST-N01A cat# 422242, AST-N01B cat# 422243, AST-N01C cat# 422244, AST-N01D cat# 422245, AST-N01E cat# 422246, AST-N01F cat# 422247, AST-N01H cat# 423069, AST-N01J cat# 423324, AST-N01K cat# 423363, AST-N01L cat# 423364, AST-N01M cat# 423392, AST-N01N cat# 423396, AST-N01P 423397, AST-N01Q cat# 423398, AST-N01S cat# 423474, AST-N101 cat# 22257, AST-N102 cat# 22258, AST-N163 cat# 410084, AST-N169 cat# 410220, AST-N181 cat# 410803, AST-N192 cat# 412602, AST-N193 cat# 412604, AST-N194 cat# 412605, AST-N195 cat# 412609, AST-N196 cat# 412860, AST-N199 cat# 412921, AST-N202 cat# 412863, AST-N203 cat# 412864, AST-N204 cat# 412865, AST-N205 cat# 412924, AST-N206 cat# 412936, AST-N207 cat# 412937, AST-N208 cat# 413062, AST-N210 cat# 412918, AST-N211 cat# 413043, AST-N212 cat# 413061, AST-N213 cat# 413063, AST-N214 cat# 413064, AST-N215 cat# 413065, AST-N216 cat# 413066, AST-N219 cat# 413082, AST-N220 cat# 413085, AST-N222 cat# 413083, AST-N223 cat# 413110, AST-N224 cat# 413111, AST-N225 cat# 413112, AST-N226 cat# 413143, AST-N227 cat# 413144, AST-N228 cat# 413145, AST-N229 cat# 413146, AST-N231 cat# 413115, AST-N232 cat# 413116, AST-N233 cat# 413117, AST-N234 cat# 413119, AST-N235 cat# 413170, AST-N238 cat# 413203, AST-N239 cat# 413204, AST-N240 cat# 413205, AST-N242 cat# 413391, AST-N243 cat# 413392, AST-N245 cat# 413394, AST-N246 cat# 413395, AST-N247 cat# 413396, AST-N248 cat# 413397, AST-N249 cat# 413572, AST-N250 cat# 413573, AST-N253 cat# 413722, AST-N255 cat# 413724, AST-N256 cat# 413725, AST-N257 cat# 413726, AST-N261 cat# 413753, AST-N263 cat# 413755, AST-N264 cat# 413864, AST-N265 cat# 413865, AST-N268

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421296, AST-P651 cat# 421586, AST-P652 cat# 421857, AST-P653 cat# 421858, AST-P654 cat# 421912, AST-P655 cat# 421913, AST-P656 cat# 421829, AST-P657 cat# 422072, AST-P658 cat# 423051, AST-P659 cat# 423050, AST-P660 cat# 423231, AST-P661 cat# 423235, AST-P662 cat# 423439, AST-P663 cat# 423646, AST-P664 cat# 424036, AST-P665 cat# 424064, AST-P666 cat# 424113, AST-P667 cat# 424183, AST-P668 cat# 424184, AST-YS01 cat# 22108, AST-YS05 cat# 411945, AST-YS08 cat# 420739, AST-YS09 cat# 423331, AST-ST02 cat# 420915, AST-ST03 cat# 421040

Identification of the person who has the power of attorney to bind the manufacturer / Nom et qualité de la personne engageant la responsabilité du fabricant :

Name / Nom : Manuela Kaul
Title / Fonction : VP Regulatory Affairs

Identification of the legal entity / Identification de l'entité légale :

Manufacturer / Fabricant : bioMerieux Inc.
Name / Nom : bioMerieux Inc.
Address / Adresse : 100 Rodolphe Street, Durham, NC, 27712,
U.S.A.

« We, the manufacturer declare that the above mentioned products comply with the Directives and their relevant implementations into all national laws of the member states into which we place the products » / « Nous, fabricant, déclarons que les produits mentionnés ci-dessus satisfont aux Directives et leurs transpositions en droit national dans les Etats Membres dans lesquels les produits sont mis sur le marché. »

Authorized representative responsible for affixing of the CE marking on the concerned products / Représentant autorisé de l'apposition du marquage CE sur le (les) produit(s) consider(s) :

Authorized Representative / Représentant Autorisé :
Name / Nom : bioMerieux, S.A.
Address / Adresse : 376 Chemin de l'Orme, 69280 Marcy l'Etoile,
France

Conformity assessment procedure used to demonstrate compliance / Procédure d'évaluation de conformité choisie :

Annex / Annexe (s) : III (section 6 excluded)



DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

Directive (s) : European Communities Council Directive 98/79/EC Concerning *In Vitro Diagnostic Medical Devices*

Device classification / Classification du dispositif :

Directive 98/79/CE : ☐ List(e) A, Annex(e) II ☐ List(e) B, Annex(e) II ☒ Other / Autre ☐ Self-testing / Autotest

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