



DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

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

Place / Lieu d'émission :

bioMérieux 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



DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

cat# 413868, AST-N269 cat# 413869, AST-N270 cat# 414162, AST-N271 cat# 414163, AST-N272 cat# 414164, AST-N274 cat# 414310, AST-N275 cat# 414313, AST-N276 cat# 414286, AST-N278 cat# 414288, AST-N279 cat# 414492, AST-N280 cat# 414531, AST-N281 cat# 414532, AST-N283 cat# 414536, AST-N285 cat# 414740, AST-N286 cat# 414778, AST-N288 cat# 414972, AST-N289 cat# 415057, AST-N290 cat# 415058, AST-N291 cat# 415062, AST-N292 cat# 415063, AST-N293 cat# 415369, AST-N295 cat# 415433, AST-N300 cat# 416241, AST-N301 cat# 416274, AST-N302 cat# 416420, AST-N303 cat# 416590, AST-N305 cat# 416596, AST-N308 cat# 416913, AST-N309 cat# 416914, AST-N311 cat# 416952, AST-N314 cat# 417027, AST-N315 cat# 417426, AST-N316 cat# 417557, AST-N317 cat# 417558, AST-N318 cat# 417952, AST-N320 cat# 418204, AST-N321 cat# 418205, AST-N322 cat# 418489, AST-N323 cat# 418602, AST-N324 cat# 418603, AST-N325 cat# 418513, AST-N326 cat# 418514, AST-N327 cat# 418515, AST-N328 cat# 418630, AST-N329 cat# 418631, AST-N330 cat# 418674, AST-N331 cat# 418675, AST-N332 cat# 418676, AST-N333 cat# 418750, AST-N336 cat# 419143, AST-N337 cat# 419076, AST-N338 cat# 419077, AST-N339 cat# 419341, AST-N340 cat# 419412, AST-N341 cat# 420061, AST-N342 cat# 420062, AST-N343 cat# 420063, AST-N344 cat# 420440, AST-N345 cat# 420580, AST-N346 cat# 420597, AST-N347 cat# 420867, AST-N348 cat# 420856, AST-N349 cat# 420859, AST-N350 cat# 421037, AST-N351 cat# 421257, AST-N352 cat# 421258, AST-N353 cat# 421297, AST-N354 cat# 421350, AST-N355 cat# 421351, AST-N356 cat# 421352, AST-N357 cat# 421451, AST-N358 cat# 421441, AST-N359 cat# 421573, AST-N360 cat# 421583, AST-N361 cat# 421584, AST-N362 cat# 421585, AST-N363 cat# 421692, AST-N364 cat# 421693, AST-N365 cat# 421830, AST-N366 cat# 421853, AST-N367 cat# 421854, AST-N368 cat# 421855, AST-N369 cat# 421856, AST-N370 cat# 422071, AST-N371 cat# 422024, AST-N372 cat# 422241, AST-N373 cat# 423007, AST-N374 cat# 423008, AST-N375 cat# 423098, AST-N376 cat# 423025, AST-N377 cat# 423031, AST-N378 cat# 423038, AST-N379 cat# 423052, AST-N380 cat# 423053, AST-N381 cat# 423054, AST-N382 cat# 423055, AST-N383 cat# 423056, AST-N384 cat# 423101, AST-N385 cat# 423097, AST-N386 cat# 423275, AST-N387 cat# 423313, AST-N388 cat# 423327, AST-N389 cat# 423334, AST-N390 cat# 423340, AST-N391 cat# 423341, AST-N392 cat# 423342, AST-N393 cat# 423343, AST-N395 cat# 423491, AST-N396 cat# 423492, AST-N397 cat# 423588, AST-N398 cat# 423591, AST-N399 cat# 423701, AST-N400 cat# 423879, AST-N401 cat# 423643, AST-N402 cat# 423644, AST-N403 cat# 423645, AST-N404 cat# 423664, AST-N405 cat# 423864, AST-N406 cat# 423869, AST-N407 cat# 423870, AST-N408 cat# 423924, AST-N409 cat# 423925, AST-N410 cat# 423926, AST-N411 cat# 423927, AST-N412 cat# 423936, AST-N413 cat# 423928, AST-N414 cat# 423933, AST-N415 cat# 423934, AST-N416 cat# 423935, AST-N417 cat# 423880, AST-N419 cat# 423948, AST-N420 cat# 424039, AST-N421 cat# 424055, AST-N422 cat# 424056, AST-N423 cat# 424042, AST-N424 cat# 424120, AST-N425 cat# 424192, AST-N426 cat# 424195, AST-N427 cat# 424196, AST-N428 cat# 424320, AST-N429 cat# 424321, AST-N430 cat# 424322, AST-N431 cat# 424323, AST-N432 cat# 424324, AST-N433 cat# 424389, AST-N434 cat# 424390, AST-N435 cat# 424391, AST-N436 cat# 424440, AST-N800 cat# 423310, AST-N801 cat# 423416, AST-N802 cat# 423706, AST-GP67 cat# 22226, AST-GP68 cat# 22231, AST-GP70 cat# 22340, AST-GP71 cat# 410750, AST-GP72 cat# 410770, AST-GP74 cat# 414971, AST-GP75 cat# 415670, AST-GP78 cat# 421051, AST-P576 cat# 22216, AST-P577 cat# 22218, AST-P580 cat# 22233, AST-P584 cat# 22252, AST-P586 cat# 22276, AST-P587 cat# 22277, AST-P589 cat# 22279, AST-P592 cat# 22287, AST-P595 cat# 22296, AST-P596 cat# 22297, AST-P597 cat# 22298, AST-P600 cat# 22313, AST-P601 cat# 22314, AST-P603 cat# 22320, AST-P604 cat# 22321, AST-P605 cat# 22325, AST-P606 cat# 22330, AST-P607 cat# 22335, AST-P608 cat# 22336, AST-P610 cat# 22351, AST-P611 cat# 22358, AST-P612 cat# 22359, AST-P613 cat# 410027, AST-P616 cat# 410223, AST-P618 cat# 410806, AST-P619 cat# 411944, AST-P621 cat# 412533, AST-P622 cat# 412645, AST-P623 cat# 412603, AST-P625 cat# 413727, AST-P626 cat# 413863, AST-P627 cat# 414124, AST-P628 cat# 414534, AST-P629 cat# 414576, AST-P631 cat# 414961, AST-P632 cat# 415059, AST-P634 cat# 415671, AST-P635 cat# 416911, AST-P636 cat# 417951, AST-P637 cat# 418583, AST-P638 cat# 418423, AST-P640 cat# 418579, AST-P641 cat# 418590, AST-P643 cat# 418671, AST-P644 cat# 418673, AST-P645 cat# 419602, AST-P646 cat# 420144, AST-P647 cat# 420610, AST-P648 cat# 420857, AST-P649 cat# 420858, AST-P650 cat#

**DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE**

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 : bioMérieux Inc.
Name / Nom : bioMérieux 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 : bioMérieux, 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

Prepared from the template Doc number 003535 - Declaration_of_Conformity_-_en_-_fr_-_Editable - Revision 02.D