

**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 :

10Jul2020

Name - Title / Nom - Fonction :

DocuSigned by:

Nathan Hardesty –
Sr. Manager Regulatory Affairs

Signature :

Signer Name: Nathan Hardesty
Signing Reason: I approve this document
Signing Time: 7/10/2020 | 5:15:55 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-GN04 cat# 22000, AST-GN09 cat# 22008, AST-GN13 cat# 22095, AST-GN14 cat# 22096, AST-GN16 cat# 22139, AST-GN48 cat# 412090, AST-GN49 cat# 412091, 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-N190 cat# 412548, 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-N201 cat# 412862, 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-N209 cat# 412938, 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-N217 cat# 413080, AST-N218 cat# 413081, 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-N230 cat# 413147, AST-N231 cat# 413115, AST-N232 cat# 413116, AST-N233 cat# 413117, AST-N234 cat# 413119, AST-N235 cat# 413170, AST-N236 cat# 413171, AST-N238 cat# 413203, AST-N239 cat# 413204, AST-N240 cat# 413205, AST-N242 cat# 413391, AST-N243 cat# 413392, AST-N244 cat# 413393, 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-N254 cat# 413723, AST-N255 cat# 413724, AST-N256 cat# 413725, AST-N257 cat# 413726, AST-N261 cat# 413753, AST-N263 cat# 413755,

**DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE**

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DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

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

Device classification / Classification du dispositif :



DECLARATION OF CONFORMITY / <i>DECLARATION DE CONFORMITE</i>

Directive 98/79/CE : <input type="checkbox"/> List(e) A, Annex(e) II <input type="checkbox"/> List(e) B, Annex(e) II <input checked="" type="checkbox"/> Other / <i>Autre</i> <input type="checkbox"/> Self-testing / <i>Autotest</i>

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



DEKLARACJA ZGODNOŚCI

Deklaracja zgodności jest ważna od dnia:

Miejsce: **bioMérieux Inc., 100 Rodolphe Street,
Durham, NC, 27712, U.S.A.**

Data wystawienia deklaracji zgodności: **10 luty 2020r.**

Nazwisko – stanowisko: **Nathan Hardesty
Sr. Manager Regulatory Affairs
(Kierownik ds. Zagadnienia Prawne)**

Podpis: **podpis nieczytelny**

Identyfikacja produktu:

Nazwa: **KARTY VITEK 2 AST**

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-GN04 cat# 22000, AST-GN09 cat# 22008, AST-GN13 cat# 22095, AST-GN14 cat# 22096, AST-GN16 cat# 22139, AST-GN48 cat# 412090, AST-GN49 cat# 412091, 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 cat# 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-N190 cat# 412548, 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-N201 cat# 412862, 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-N209 cat# 412938, 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-N217 cat# 413080, AST-N218 cat# 413081, 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-N230 cat# 413147, AST-N231 cat# 413115, AST-N232 cat# 413116, AST-N233 cat# 413117, AST-N234 cat# 413119, AST-N235 cat# 413170, AST-N236 cat# 413171, AST-N238 cat# 413203, AST-N239 cat# 413204, AST-N240 cat# 413205, AST-N242 cat# 413391, AST-N243 cat# 413392, AST-N244 cat# 413393,

**DEKLARACJA ZGODNOŚCI**

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**DEKLARACJA ZGODNOŚCI**

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Identyfikacja osoby, która posiada pełnomocnictwo do wystawiania niniejszej deklaracji w imieniu producenta:

Nazwisko: **Manuela KAUL**
Stanowisko: **VP Global Clinical & Regulatory Affairs**
(Wiceprezes ds. Globalnych Zagadnień Prawnych oraz Klinicznych)

Identyfikacja osoby prawnej:

Producent: **bioMérieux Inc.**
Nazwa: **bioMérieux Inc.**
Adres: **100 Rodolphe Street, Durham, NC, 27712, U.S.A.**

My, producent, niniejszym oświadczamy, że produkty wymienione powyżej spełniają wymagania dyrektyw oraz ich stosownych odpowiedników w ustawach wewnętrznych Państw Członkowskich, do których dostarczamy te produkty.



DEKLARACJA ZGODNOŚCI

Autoryzowany przedstawiciel odpowiedzialny za umieszczenie oznakowania CE na przedmiotowych produktach:

Nazwa: bioMérieux S.A.
Adres: 376 Chemin de l'Orme,
69280 Marcy l'Etoile, FRANCJA

Procedura oceny zgodności użyta do stwierdzenia zgodności:

Załącznik (i): III (z wyłączeniem rozdziału 6)
Dyrektywa (y): Dyrektywa 98/79/CE Parlamentu Europejskiego i Rady z dnia 27 października 1998 r. w sprawie wyrobów medycznych do diagnostyki in vitro

Klasyfikacja produktu:

Dyrektywa 98/79/CE: ☐ Lista A, Załącznik II ☐ Lista B, Załącznik II ☒ Inne ☐ Wyroby do samokontroli

Przygotowano na podstawie szablonu, dokument nr: 029096– Deklaracja zgodności – en – fr – wersja 02.D