

CE MARKING DECLARATION OF CONFORMITY DÉCLARATION CE DE CONFORMITÉ

for *in vitro* diagnostic medical devices covered by Directive 98/79/EC
pour les dispositifs médicaux de diagnostic in vitro relevant de la Directive n°98/79/CE

Device(s) category:

Nom(s) du (des) dispositif(s) :

Devices - Rapid tests (List attached)

Dispositifs – Tests rapides (Liste ci-joint)

Classification of the device(s):

Classification du (des) dispositif(s) :

<input type="checkbox"/> device of list A annex II <i>dispositif de l'annexe II liste A</i>	<input type="checkbox"/> device of list B annex II <i>dispositif de l'annexe II liste B</i>
<input type="checkbox"/> device for self-testing not listed in annex II <i>autotest hors annexe II</i>	<input type="checkbox"/> device for self-testing listed in annex II <i>autotest de l'annexe II</i>
<input checked="" type="checkbox"/> other device (all devices except annex II and self-testing devices) <i>autre dispositif (tous les dispositifs sauf dispositifs de l'annexe II et autotests)</i>	

Note : Devices corresponding to the Class B according to the 2017/746 EU regulation

Note: Dispositifs de classe B selon le règlement UE 2017/746

- 1) **We, VEDALAB, certify that the above-mentioned device is manufactured by VEDALAB, located ZAT du Londeau, Rue de l'Expansion, Cerisé, B.P.181, 61006 Alençon cedex, France. VEDALAB is exclusively responsible for this CE marking declaration of conformity.**

Nous, soussignés, VEDALAB, certifions que le dispositif mentionné ci-dessus est fabriqué par la société VEDALAB, située ZAT du Londeau, Rue de l'Expansion, Cerisé, B.P.181, 61006 Alençon cedex, France. VEDALAB est exclusivement responsable de cette déclaration CE de conformité.

- 2) **This device complies with all Essential Principles and Requirements for Safety and Performance of the IVDD European Directive 98/79/CE.**

Ce dispositif est conforme à tous les principes et exigences essentiels de la Directive Européenne DMDIV 98/79/CE pour la sûreté et la performance.

- 3) **This compliance has been properly documented according to the following conformity assessment procedure:**

Ces obligations ont été documentées à partir de la procédure de conformité suivante :

<input checked="" type="checkbox"/> Annex III excluding part 6 <i>Annexe III excluant point 6</i>	<input type="checkbox"/> Annex III including part 6 <i>Annexe III incluant point 6</i>	
<input type="checkbox"/> Annexe IV <i>Annexe IV</i>	<input type="checkbox"/> Annex V <i>Annexe V</i>	<input type="checkbox"/> Annex VII <i>Annexe VII</i>

<input type="checkbox"/> Examination by a notified body / Examen par un organisme notifié : Name of the notified body / Nom de l'organisme notifié "name" Identification number / Numéro d'identification : "number" Address / Adresse : "address" Certificate n° / certificat n° : "number" Valid until / Valide jusqu'à: "date"

- 4) **Expiry date/Valable jusqu'au: May 26th, 2027 / 26 mai 2027**

ALENÇON,
On April 19th, 2022
Le 19 avril 2022

Raphaël DONATI

C.E.O.

Président Directeur Général

VEDA.LAB
Rue de l'Expansion
ZAT du Londeau - Cerisé - BP 181
61006 Alençon cedex - France
☎ (33) 2 33 27 56 25 - ☎ (33) 2 33 27 70 60
SIRET 382 394 559 00027

FOR 161 m10

Siège social : Rue de l'Expansion - ZAT du Londeau - Cerisé - B.P. 181 - 61006 Alençon Cedex - France
Tél. : **(33) 2 33 27 56 25** - Fax : (33) 2 33 27 70 60 - www.vedalab.com - E-mail : veda.lab@wanadoo.fr

Liste des dispositifs (1/2) / List of devices (1/2)

Dispositifs "autres dispositifs" (tous les dispositifs sauf dispositifs de l'annexe II et autotests) :

Devices of « other devices » (all devices except annex II and self-testing devices) :

References	Nom (Name)
29001 / 29001-10T / 29071 / 29071-10T 29071-4 / 29071-4-10T / 29071-MS-4 / 29071-MS-4-10T	ADENO-CHECK-1
29031 / 29031-10T	ADENO-CHECK-1 STRIP
999981B-3L / 999981B-3L-10T 999981W-3L / 999981W-3L-10T	COMBO ALT+AST-CHECK-1
34001 / 34001-10T / 34071 / 34071-10T 34181-3L-S / 34181-3L-S-10T	CRP-CHECK-1
34031 / 34031-10T / 34035 / 34038	CRP-CHECK-1 STRIP
HS34051 / HS34051-10T / HS34071 / HS34071-10T	HS-CRP-CHECK-1
25001 / 25001-10T / 25081 / 25081-10T	FRT-CHECK-1
LS25051 / LS25051-10T / LS25081 / LS25081-10T	LS-FRT-CHECK-1
11001 / 11001-10T / 11071 / 11071-10T 11071-4 / 11071-4-10T	FSH-CHECK-1
11031 / 11031-10T	FSH-CHECK-1 STRIP
901001 / 901001-10T / 901071 / 901071-10T	GIARDIA-CHECK-1
64001 / 64001-10T / 64071 / 64071-10T	GDH-CHECK-1
150051 / 150051-10T / 150081 / 150081-10T	GLUTEN-CHECK-1
3271 / 3271-10T	β-hCG-CHECK-1
3001 / 3001-10T / 3071 / 3071-10T / 3071-10 / 3071-10-10T 3071-4 / 3071-4-10T / 3071-4-10 / 3071-4-10-10T / 3071-MS-4 / 3071-MS-4-10T / 3051B / 3051B-10T / 3071B / 3071B-10T	BABYCHECK-1
3181 / 3181-10T	hCG-CHECK-1
3035 / 3036	BABY-CHECK-1 STRIP
3041 / 3041-10T	BABYCHECK-1 DUO
3041B / 3041B-10T	BABYCHECK-1 DUO 5-1000
3061-1000	hCG-1000 midstream test
3071-1000	hCG-CHECK-1000
18001 / 18001-10T / 18071 / 18071-10T / 18051 / 18051-10T / 18081 / 18081-10T	IgE-CHECK-1
18031 / 18031-10T	IgE-CHECK-1 STRIP
16001 / 16001-10T / 16071 / 16071-10T 16071-MS-B / 16071-MS-B-10T	IM-CHECK-1
5001 / 5001-10T / 5071 / 5071-10T 5071-4 / 5071-4-10T / 5071-MS-4 / 5071-MS-4-10T	L-CHECK-1
5031 / 5031-10T	L-CHECK-1 STRIP
27001 / 27001-10T / 27071 / 27071-10T 27071-4 / 27071-4-10T	M-ALBU-CHECK-1
27031 / 27031-10T	M-ALBU-CHECK-1 STRIP
9001 / 9001-10T / 9051 / 9051-10T / 9081 / 9081-10T	PROLAC-CHECK-1
30001 / 30001-10T / 30071 / 30071-10T 30071-4 / 30071-4-10T / 30071-MS-4 / 30071-MS-4-10T	ROTA-CHECK-1
30031 / 30031-10T	ROTA-CHECK-1 STRIP
30041 / 30041-10T / 302971 / 302971-10T	DUO ROTA-ADENOVIRUS-CHECK-1
31001 / 31001-10T / 31071 / 31071-10T 31071-4 / 31071-4-10T / 31071-MS-4 / 31072-MS-4-10T	RSV-CHECK-1
6001 / 6001-10T / 6071 / 6071-10T 6071-4 / 6071-4-10T / 6071-MS-4 / 6072-MS-4-10T	STREP A-CHECK-1
6031 / 6031-10T	STREP A-CHECK-1 STRIP
32001 / 32001-10T / 32071 / 32071-10T	TOXIN A-CHECK-1
32031 / 32031-10T	TOXIN A-CHECK-1 STRIP
37001 / 37001-10T / 37071 / 37071-10T	TOXIN B-CHECK-1
323771-3L / 323771-3L-10T	COMBO TOXIN A+B-CHECK-1
32041 / 32041-10T	DUO TOXIN A+B-CHECK-1
326471T / 326471T-10T	TRIO TOXIN A/B/GDH-CHECK-1
21051 / 21051-10T / 21081 / 21081-10T 21081-4-2 / 21081-4-2-10T	TSH-CHECK-1 (Adult version)
21101 / 21101-10T / 21181 / 21181-10T 21181-4-2 / 21181-4-2-10T	TSH-CHECK-1 (Pediatric version)

Liste des dispositifs (2/2) / List of devices (2/2)

Dispositifs “autres dispositifs” (tous les dispositifs sauf dispositifs de l’annexe II et autotests) :

Devices of « other devices » (all devices except annex II and self-testing devices) :

References	Nom (Name)
19201 / 19201-10T / 19271 / 19271-10T 19271-4 / 19271-4-10T	DRUG-CHECK-1 AMPHETAMINE
19234 / 19234-10T	DRUG-CHECK-1 AMPHETAMINE STRIP
19601 / 19601-10T / 19671 / 19671-10T 19671-4 / 19671-4-10T	DRUG-CHECK-1 BARBITURATES
19634 / 19634-10T	DRUG-CHECK-1 BARBITURATES STRIP
19701 / 19701-10T / 19771 / 19771-10T 19771-4 / 19771-4-10T	DRUG-CHECK-1 BENZODIAZEPINE
19731 / 19731-10T	DRUG-CHECK-1 BENZODIAZEPINE STRIP
191001 / 191001-10T / 191071 / 191071-10T 191071-4 / 191071-4-10T	DRUG-CHECK-1 BUPRENORPHINE
191031 / 191031-10T	DRUG-CHECK-1 BUPRENORPHINE STRIP
19301 / 19301-10T / 19371 / 19371-10T 19371-4 / 19371-4-10T	DRUG-CHECK-1 COCAINE
19334 / 19334-10T	DRUG-CHECK-1 COCAINE STRIP
19501 / 19501-10T / 19571 / 19571-10T 19571-4 / 19571-4-10T	DRUG-CHECK-1 METHADONE
19531 / 19531-10T	DRUG-CHECK-1 METHADONE STRIP
19001 / 19001-10T / 19071 / 19071-10T 19071-4 / 19071-4-10T	DRUG-CHECK-1 METHAMPHETAMINE
19034 / 19034-10T	DRUG-CHECK-1 METHAMPHETAMINE STRIP
19101 / 19101-10T / 19171 / 19171-10T 19171-4 / 19171-4-10T	DRUG-CHECK-1 MORPHINE
19131 / 19131-10T	DRUG-CHECK-1 MORPHINE STRIP
19901 / 19901-10T / 19971 / 19971-10T 19971-4 / 19971-4-10T	DRUG-CHECK-1 TCA
19931 / 19933 / 19934	DRUG-CHECK-1 TCA STRIP
19401 / 19401-10T / 19471 / 19471-10T 19471-4 / 19471-4-10T	DRUG-CHECK-1 THC
19431 / 19431-10T	DRUG-CHECK-1 THC STRIP
19041 / 19041-10T	DRUG-CHECK-1 DUO Methamphetamine Morphine
19051 / 19051-10T	DRUG-CHECK-1 DUO Methamphetamine THC
19441 / 19441-10T	DRUG-CHECK-1 DUO THC Cocaine