REPUBLIQUE FRANCAISE

CCI PARIS ILE-DE-FRANCE

Direction Générale Adjointe - Services aux Entreprises et Développement International
Direction des réseaux et partenariats internationaux
Service CLV

Certificat de Libre Vente pour l'exportation vers les pays non membres de l'Union Européenne

Free sale certificate for exportation to the non-EC Member States

dispositifs médicaux de diagnostic in vitro relevant de la directive n°98/79/CE

in vitro diagnostic medical devices covered by Directive 98/79/EC

REPUBLIQUE FRANÇAISE
LEGALISATION
(DECRET N° 2007-1205 DU 10 AOUT 2007)
DESTINATION DE L'ACTE (PAYS OU AUTORITE)
VIETNAM
DATE 15 AVR. 2022
NOM ET QUALITE DE L'AGENT : El Mehdi OUANES
BUREAU DES LEGALISATIONS
SIGNATURE
ET CACHET OBLIGATOIRE :
MINISTERE DES AFFAIRES ETRANGERES

PARTIE A COMPLETER PAR LE DEMANDEUR
Section to be completed by the applicant

Catégorie(s) du(des) dispositif(s) : Immunology
Device(s) category : Immunology

Nombre de page en annexe : 7
Page in annex : 7

La désignation du(des) dispositif(s) apparaît sur la déclaration(s) CE de conformité du fabricant ou du mandataire
The name of the device(s) appears on the EC declaration(s) of conformity of the manufacturer or the authorized representative

Classification du(des) dispositif(s) :
Classification of the device(s) :

☒ **dispositif de l'annexe II liste A**
device of list A annex II

☐ **autotest hors annexe II**
device for self-testing not listed in annex II

☒ **dispositif de l'annexe II liste B**
device of list B annex II

☒ **autre dispositif (tous les dispositifs sauf dispositifs de l'annexe II et autotests)**
other device (all devices except annex II and self-testing devices

Nom et adresse du fabricant ou du mandataire :
Name and address of the manufacturer or the authorized representative:
BIOMERIEUX SA, 376 Chemin de l'Orme, 69280 Marcy l'Etoile – France
Legal manufacturer/Fabricant légal **BIOMERIEUX SA,** 376 Chemin de l'Orme, 69280 Marcy l'Etoile – France

Nom et adresse du site de production (facultatif):
Name and address of Production site (optional):

Je soussignée Manuela KAUL, VP Regulatory Affairs, certifie que les informations mentionnées ci-dessus sont exactes et que les dispositifs médicaux de diagnostic in vitro figurant sur la(les) déclaration(s) CE de conformité sont marqués CE sous ma responsabilité au titre de la directive n°98/79/CE et répondent aux exigences essentielles de santé et de sécurité.
I the undersigned Manuela KAUL, VP Regulatory Affairs, declare that the information above-mentioned is correct and the in vitro diagnostic medical devices on the EC declaration(s) of conformity are CE marked under my responsibility within the meaning of the European directive n°98/79/EC and fulfil the essential requirements of health and safety.

Date :2022-01-18

Signature :

DocuSigned by:
Signer Name: Manuela KAUL
Signing Reason: I approve this document
Signing Time: 1/18/2022 | 9:52:04 AM CET
9CF4CB25EF8C4C80B1A742856CE59B23

PARTIE RESERVEE A LA CCIR PARIS IDF
Section reserved for the administration

Les dispositifs médicaux de diagnostic in vitro marqués CE en conformité avec la directive 98/79/CE peuvent être mis sur le marché en France et dans les autres Etats membres de l'Union Européenne et parties à l'accord sur l'espace économique européen, et être exportés vers les pays tiers. Ce certificat de libre vente est valide à concurrence du maintien, par le fabricant des dispositifs concernés, d'une déclaration de conformité (autre dispositifs), accompagnée le cas échéant, des certificats nécessaires délivrés par un organisme notifié (dispositif de l'annexe II liste A et liste B, autotests hors annexe II). Ce certificat de libre vente est utilisable uniquement à des fins d'exportation hors Union européenne.

24-01-2...

CCIR Paris IDF / DGA-AIE
Service des CLV
9, rue Coquillière
75001 PARIS

Le Responsable du département des Facilitations du Commerce Extérieur CCIR Paris IDF

Pour le président, Sofiane BOUHADEF

The in vitro diagnostic medical devices CE marked in conformity with the directive 98/79/EC can be placed on the French market and in the other Member states of the European Union and part of the European Free Trade Association, and be exported in the non-EC Member States. This free sale certificate is valid until the maintenance, by the manufacturer of the ncerned devices, of an CE declaration of conformity (other devices) together with when appropriate, the certificates delivered by a notified body (devices of list A and B, annex II, devices for self-testing not listed in annex II). This free sale certificate can only be used for exportation outside European Union.

ĐẠI SỨ QUÁN CHXHCNVN TẠI CH PHÁP
AMBASSADE DE LA R.SDU VIETNAM EN REPUBLIQUE FRANCAISE
CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
Certificat/Légalisation consulaire

1. Quốcgia **VIỆT NAM**
   Pays
   Giấy tờ tài liệu này
   Ce (ces) document (s)
2. Do Ông (bà) **El-Mehdi OUANES**
   ký
   a été signé par
3. Với chức danh **CÁN BỘ NGOẠI GIAO**
   en tant que
4. Và con dấu của **BỘ NGOẠI GIAO PHÁP**
   avec le tampon de
   Được chứng nhận/hợp pháp hóa lãnh sự
   a été (ont été) cerrtifié (s)/légalisé (s)
5. Tại **PARIS** 6. Ngày **25/04/2022**
   à le
7. Cơ quan cấp **ĐSQ VIỆT NAM TẠI PHÁP**
   par
8. Số **532/2022/OUA**
   N°

T/L ĐẠI SỨ/*P.O. DE L'AMBASSADEUR*
BÍ THƯ THỨ BA/TROISIÈME SECRÉTAIRE

ĐẠI SỨ QUÁN C.H.X.H.C.N VIỆT NAM TẠI CỘNG HÒA PHÁP ★ PHÒNG LÃNH SỰ ★

Phạm Thái Hòa

					Certificate delivered by the Notified Body: LNE-G-MED - CE 0459		
Product code	Product name	Device classification	Conformity assessement procedure	Manufacturing site name	QA Certificate N°	Design examination Certificate N°	EC type examination Certificate N°
IMMUNOASSAYS - VIDAS (PC) Instrument, Accessories, Software							
410417	VIDAS®	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
99735	VIDAS analyzer	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
93567	VIDAS® Lens Cleaner	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
423447	VIDAS PC v4.9 Windows 10 update	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
413453	VIDAS® PC Update Kit V4.7.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
415364	VIDAS® PC SOFT RP5800 V4.7.1 (BCI Link 4.0.0.22)	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
417894	VIDAS® PC V4.7.1 (BCI Link 4.0.0.22) UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
IMMUNOASSAYS - miniVIDAS Instrument, Accessories, Software							
410416	mini VIDAS®	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
99737	mini VIDAS analyzer	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
93567	VIDAS® Lens Cleaner	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
413452	miniVIDAS® Update Kit1 V5.6.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
414200	miniVIDAS® Update Kit2 V5.6.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423117	MINI VIDAS FLASH CARD V5.6.1	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
93493	mini VIDAS UPDATE KIT V5.2.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
93605	mini VIDAS® V5.3.0 Soft Kit	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
IMMUNOASSAYS - VIDAS 3 Instrument, Accessories, Software							
412590	VIDAS® 3	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
412500	VIDAS® 3 Assay dilution cup	except Annex II and self-testing devices	Annex III (section 6 excluded)	20	N/A	N/A	N/A
412501	VIDAS® 3 Sample tips	except Annex II and self-testing devices	Annex III (section 6 excluded)	19	N/A	N/A	N/A
416460	VIDAS® 3 RP5800 DVD MASTER V1.1.2 (BCI Link 4.0.0.22)	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
419001	VIDAS® 3 V.1.1.4 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A

					Certificate delivered by the Notified Body: LNE-G-MED - CE 0459		
Product code	**Product name**	**Device classification**	**Conformity assessement procedure**	**Manufacturing site name**	**QA Certificate N°**	**Design examination Certificate N°**	**EC type examination Certificate N°**
419002	VIDAS® 3 RP5800 DVD MASTER V1.1.4	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
421731	VIDAS® 3 V.1.2 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
422105	VIDAS® 3 1.2.1 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423135	VIDAS 3 V1.3 DVD SW UPDATE	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423146	VIDAS 3 V1.2.2 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423630	VIDAS V3 1.3.2	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423694	VIDAS 3 V1.4 Software	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
IMMUNOASSAYS - VIDAS Reagents							
30115	VIDAS® Protein C	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30117	VIDAS® HIV P24 II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9121	N/A
30118	VIDAS® *C. difficile* Toxin A & B	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30125	VIDAS® *C. difficile* GDH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30192	VIDAS® *H. pylori* IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30202	VIDAS® Toxo IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9111
30202-30	VIDAS® Toxo IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9111
30204	VIDAS® CMV IgG	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9126
30205	VIDAS® CMV IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9127
30210	VIDAS® TOXO IgG II	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30211	VIDAS® TOXO Compétition	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	8329
30214	VIDAS® RUB IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9110
30217	VIDAS® Varicella-Zoster IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30218	VIDAS® Mumps IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30219	VIDAS® Measles IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30221	VIDAS® RUB IgG II	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A

					Certificate delivered by the Notified Body: LNE-G-MED - CE 0459		
Product code	Product name	Device classification	Conformity assessement procedure	Manufacturing site name	QA Certificate N°	Design examination Certificate N°	EC type examination Certificate N°
30222	VIDAS® TOXO IgG AVIDITY	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30235	VIDAS® EBV EBNA IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30236	VIDAS® EBV VCA/EA IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30237	VIDAS® EBV VCA IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30305	VIDAS® HBe/Anti-HBe	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9138	N/A
30307	VIDAS® HAV IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30308	VIDAS® Anti-HCV	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	23068	N/A
30312	VIDAS® Anti-HAV Total	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30314	VIDAS® Anti-HBc Total II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	8470	N/A
30315	VIDAS® HBs Ag Ultra	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	8325	N/A
30317	VIDAS® HBs Ag Ultra Confirmation	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9120	
30318	VIDAS® Anti-HBs Total II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	26813	N/A
30319	VIDAS® Lyme IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30320	VIDAS® Lyme IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30400	VIDAS® TSH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30402	VIDAS® FT3	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30403	VIDAS® T3	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30404	VIDAS® T4	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30405	VIDAS® HCG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30406	VIDAS® LH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30407	VIDAS® FSH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30409	VIDAS® Progesterone	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30410	VIDAS® Prolactin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A

					Certificate delivered by the Notified Body: LNE-G-MED - CE 0459		
Product code	Product name	Device classification	Conformity assessement procedure	Manufacturing site name	QA Certificate N°	Design examination Certificate N°	EC type examination Certificate N°
30411	VIDAS® Ferritin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30413	VIDAS® AFP	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30419	VIDAS® TOTAL IgE	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30420	VIDAS® ß2 Microglobulin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30421	VIDAS® CK-MB	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30426	VIDAS® CA 125 II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30427	VIDAS® CA 19-9™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30428	VIDAS® TPSA	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30429	VIDAS® CA 15-3®	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30431	VIDAS® Estradiol II	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30436	VIDAS® vWF	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30439	VIDAS® HBc IgM II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9119	N/A
30440	VIDAS® FPSA	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30441	VIDAS® TSH3	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30443	VIDAS® HIV DUO Ultra	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9123	N/A
30444	VIDAS® HIV P24 II Confirmation	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9122	N/A
30446	VIDAS® Myoglobin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30447	VIDAS® HIV DUO Quick	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9124	N/A
30448	VIDAS® TROPONIN I Ultra	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30450	VIDAS® B.R.A.H.M.S PCT™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30450-30	VIDAS® B.R.A.H.M.S PCT™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30450-86	VIDAS® B.R.A.H.M.S PCT™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30451	VIDAS® Cortisol S	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A

					Certificate delivered by the Notified Body: LNE-G-MED - CE 0459		
Product code	Product name	Device classification	Conformity assessement procedure	Manufacturing site name	QA Certificate N°	Design examination Certificate N°	EC type examination Certificate N°
30451-30	VIDAS® Cortisol S	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30453	VIDAS® CEA (S)	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30455	VIDAS® D-Dimer Exclusion II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30455-02	VIDAS® D-Dimer Exclusion II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30455-30	VIDAS® D-Dimer Exclusion II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30458	VIDAS® NT-proBNP2	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30458-30	VIDAS® NT-proBNP2	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30459	VIDAS® FT4	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30461	VIDAS® Anti-TPO	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30462	VIDAS® Anti-Tg	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30463	VIDAS® 25 OH Vitamin D TOTAL	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30603	VIDAS® Digoxin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30706	Quality Control VIDAS® (QCV)	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
413557	VIDAS® CMV IgG Avidity II	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
414320	VIDAS® Testosterone II	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
415386	VIDAS® High sensitive Troponin I	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
415386-30	VIDAS® High sensitive Troponin I	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
417011	VIDAS® Anti-Müllerian Hormone	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
418115	VIDAS® Anti-HEV IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
418116	VIDAS® Anti-HEV IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
422010	VIDAS® PTH (1-84)	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A

					Certificate delivered by the Notified Body: LNE-G-MED - CE 0459		
Product code	Product name	Device classification	Conformity assessement procedure	Manufacturing site name	QA Certificate N°	Design examination Certificate N°	EC type examination Certificate N°
423833	VIDAS® SARS-COV-2 IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423834	VIDAS® SARS-COV-2 IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
421172	VIDAS® NEPHROCHECK®	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
421172-03	VIDAS® NEPHROCHECK®	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423111	VIDAS® TB-IGRA	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423077	VIDAS® DENGUE NS1 Ag	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423078	VIDAS® Anti-DENGUE IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423079	VIDAS® Anti-DENGUE IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423833	VIDAS® SARS-COV-2 IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423834	VIDAS® SARS-COV-2 IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
424114	VIDAS® SARS-COV-2 IgG II	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
424069	VIDAS IFNg QC Panel	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
IMMUNOSEROLOGY - Reagents							
66581	SERUM FREE	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
72331	ASD-Kit	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
75361	Toxo-ISAGA	Annex II-B	An.V + VII (sec. 5 excluded)	1	9137	N/A	9125
79322	Toxo-ISAGA IgA	Annex II-B	An.V + VII (sec. 5 excluded)	1	9137	N/A	9100

Production Site code	Name	Address	Country
1	BIOMERIEUX S.A.	376 Chemin de l'Orme - 69280 Marcy l'Etoile	France
2	BIOMERIEUX S.A.	5 rue des Aqueducs - 69290 CRAPONNE	France
3	BIOMERIEUX S.A.	3 route de Port Michaud - 38390 LA BALME LES GROTTES	France
4	BIOMERIEUX S.A.	Centre Christophe Mérieux - 5 rue des Berges - 38024 GRENOBLE CEDEX 01	France
5	BIOMERIEUX S.A.	138 rue Louis Pasteur, Parc Technologique Delta Sud - 09340 VERNIOLLE	France
6	BIOMERIEUX S.A.	Route de Dol - 35270 COMBOURG	France
7	bioMérieux, Inc.	100 Rodolphe Street, Durham, North Carolina 27712	USA
8	BioMérieux, Inc.	595 Anglum Road, Hazelwood, Missouri 63042	USA
9	BIOMERIEUX ESPANA S.A.	C/Isaac Newton n° 6 - Parque Técnologico de Madrid Tres Cantos 28760	Spain
10	BIOMERIEUX Italia S.p.A.	Via di Campigliano, 58 - Ponte a Ema, 50012 Bagno a Ripoli (Firenze)	Italy
11	bioMerieux (Shanghai) Compagny Limite	No.4633, Pusan Road, Pudong District, SHANGHAI, CHINA, 201315	China
12	ELITechGroup Inc.	370 West 1700 South - Logan, Utah 84321	USA
13	RAL DIAGNOSTICS	Site Montesquieu, Bordeaux Technopolis - 33650 Martillac	France
14	Orion Diagnostica Oy	Koivu-Mankkaan tie 6 B, P.O. Box 83, Espoo, FI-02101	Finland
15	Revere Plastic Systems, LLC	1452 Rowe Parkway, Poplar Bluff, Missouri, 69301	USA
16	Gerresheimer	650 Highway 74 South - Peachtree City, GA 30269	USA
17	MEDISIZE CZ s.r.o	Tovami 560 274 15 Trhové Sviny	Czech Republic
18	Kratos Analytical Ltd	Wharf Side, Trafford Wharf Road, Manchester, M17 1GP	United-Kingdom
19	Eppendorf AG	Barkhausenweg 1, 22339 Hamburg - Germany	Germany
20	PLASTIBELL PHARM II	150 Z.I. La Plaine, B.P. 16, 01580 Izernore - France	France
21	Sanmina-SCI AB	Svedjevägen 12, SE-891 23 Örnsköldsvik	Sweden
22	Hach Company	100 Dayton Avenue, Ames, IA 50010	USA
23	Qnostics Ltd	2 Block 4.01, Kelvin Campus, West Scotland Science Park, Glasgow G20 0SP	United-Kingdom
24	STRATEC Consumables GmbH	Sonystrabe 20, 5081 Anif	Austria
25	REMEL	12076 Sante Fe Drive, Lenexa, KS 66212 USA	United States