TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
1	PCL. Inc., Republic of Korea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	PCL COVID19 Ag Rapid FIA; PCL COVID19 IgG/IgM Rapid Gold	PCL COVID19 Ag Rapid FIA is an in vitro diagnostic medical device applying dual antibody sandwich reaction and fluorescence immunochromatographic assay to qualitatively detect SARS CoV 2 antigen in human oropharyngeal / nasopharyngeal specimens and sputum specimens. PCL COVID19 IgG/IgM Rapid Gold is an in vitro diagnostic medical device for qualitative detection of IgG and IgM antibodies of COVID19 infection in human serum, plasma, venous blood and capillary blood. For professional use only. Internal admin-No.: PCL-07, PCL-07-01	DE - GERMANIA
2	SCREEN ITALIA SRL, Italia	NA	info@screenitalia.it	SCREEN TEST COVID-19 - 2019-NCOV IGG/IGM RAPID TEST CASSETTE	---	IT – ITALIA
3	BIOPLASTIC SOCIETA IN ACCOMANDITA SEMPLICE DI PETRALIA MARIO, Italia	NA	VIA ALESSANDRO DUDAN 9, ROMA,00143	COVID-19 IGG/IGM RAPID TEST	---	IT – ITALIA
4	Swedicine AB, Suedia	NA	Beiar@.Swedicine.se	COVID-19	---	SE – SUEDIA
5	Roche Molecular Systems, Inc., SUA	Roche Diagnostics, GmbH, Germania	ralf.zielenski@roche.com	SARS-CoV-2 Control Kit	cobas® SARS-CoV-2 test for use on the cobas® 6800/8800 Systems is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples.	DE - GERMANIA
6	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 IgG Antibody (ELISA)	The kit Assay is an Enzyme immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human Serum or Plasma	DE - GERMANIA
7	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 IgM Antibody (ELISA)	The kit Assay is a Enzyme linked immuno Assay for qualitative detection of IgM antibody to the new coronavirus in human Serum and plasma	DE - GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
8	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 IgG/IgM Antibody (Colloidal Gold)	Immunchromatographic technology for qualitative determination of IgG/IgM antibodies against SARS-CoV-2 in human Serum, Plasma or whole blood	DE - GERMANIA
9	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 Nucleic Acid Real Time PCR	The PCR test is used for the qualitative detection of SARS-CoV-2 nucleic acid by targeting OFRlab Region, N and E protein genes of the viral Genome	DE - GERMANIA
10	PCL. Inc., Republic of Korea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	PCLMD# nCoV one step RT-PCR kit	The PCLMDTM nCoV one step RT-PCR Kit is a qualitative real-time reverse transcription PCR (RT-PCR) IVD medical device for the detection of SARS-CoV-2 in human nasopharyngeal specimen. For professional use only.	DE - GERMANIA
11	BioCore Co.Ltd., Republic of Korea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	BioCore 2019-nCoV Real Time PCR Kit	This product qualitatively confirms the presence or absence of a new coronavirus (SARS CoV2, Covid-19) using reverse-transcription Real Time Polymerase Chain Reaction in sputum, oropharyngeal and nasopharyngeal specimens. Internal admin-No.: BIC-01	DE - GERMANIA
12	QIAGEN GmbH, Germania	NA	RegulatoryAffairs@qiagen.com	QIAstat-Dx Respiratory SARS-CoV-2 Panel	The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative test intended for analyzing nasopharyngeal swab (NPS) samples for the presence of viral or bacterial nucleic acids. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is able to accept both dry swabs a and transport medium liquid samples. The assay is designed for use with the QIAstat-Dx Analyzer 1.0 for integrated nucleic acid extraction and multiplex real-time RT-PCR detection.	DE - GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
13	BGI EUROPE A/S, Danemarca	NA	Ole Maaløes Vej 3 2200 København N	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	The kit is a qualitative in vitro nucleic acid amplification assay to detect the new coronavirus identified in China in 2019 using Reverse transcription PCR in specimen of Throat swab and Bronchoalveolar Lavage Fluid (BALF)from suspects.In end of 2019, some pneumonia cases were reported in Wuhan, China and the pathogen was confirmed as a new strain. World Health organization has named the newly identified coronavirus as 2019-nCoV. Although more intensive researches must be conducted later to well understand the virus, in response to the emergency in disease control, simple and rapid kit is necessary to identify the virus timely and implement efficient interventions to contain the spread. The kit will qualitatively detect the nucleic acid of 2019-nCoV in specimen from suspects enabling to assess the infection situation of 2019-nCoV in suspects in clinical and public health practice.	DK - DANEMARCA
14	HANGZHOU ALLTEST BIOTECH CO., LTD., China	ALCOOLTEST MARKETING ITALY S.R.L., Italia	ALCOOLTEST@PEC.IT	AMIINCP-402S - 2019-NCOV FIRNGERTIP	---	IT - ITALIA
15	HANGZHOU ALLTEST BIOTECH CO., LTD., China	ALCOOLTEST MARKETING ITALY S.R.L., Italia	ALCOOLTEST@PEC.IT	2019-NCOV CORONA VIRUS AMI-INCP402	---	IT – ITALIA
16	INTERMEDICAL S.R.L., Italia	NA	INTERMEDICALSRL@CGN.LEGALMAIL.IT	2019-NCOV IGG/IGM	---	IT – ITALIA
17	Hangzhou Laihe Biotech Co., Ltd., China	Riomavix S.L., Spania	Calle de Almansa 55, 1D, 28039 Madrid	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	The LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is intended for the qualitative detection of IgM/IgG antibodies against novel coronavirus in human serum, plasma or whole blood from patients with clinical suspicion of Novel coronavirus (2019-nCoV) infection. For in vitro diagnostic use	ES - SPANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
18	CORIS BioConcept, Belgia	NA	Science Park CREALYS Rue Jean Sonet, 4 5032 Gembloux Belgium	COVID-19 Ag Respi-Strip	COVID-19 Ag Respi-Strip: In vitro rapid diagnostic test for the detection of SARS-CoV-2 antigen in nasopharyngeal secretions	BE – BELGIA
19	Shenzhen Lvshiyuan Biotechnology Co., Ltd	OBELIS S.A., Belgia	mail@obelis.net	COVID-19(2019-nCoV) Coronavirus lgG/IgM Rapid Test Kit	COVID-19(2019-nCoV) Coronavirus lgG/IgM Rapid Test Kit is used to qualitatively detect lgG and IgM antibodies to SARS-CoV-2 coronavirus in human serum, plasma or whole blood in vitro	BE – BELGIA
20	M monitor Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	Isopollo® COVID-19 detection kit (real-time); Isopollo® COVID-19 detection kit (premix)	Isopollo® COVID-19 detection kit (real-time) and Isopollo® COVID-19 detection kit (premix) are in vitro diagnostic reagent kits for qualitative analysis to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection from extracted RNA of clinical specimens of smeared material from human nasopharyngeal and oropharyngeal swab, sputum, and bronchoalveolar lavage by RT-LAMP (Reverse transcription loop-mediated isothermal amplification). For professional use only. Internal Admin-No.: MMO-04; MMO-04-01.	DE – GERMANIA
21	GENOBIO PHARMACEUTICAL CO, LTD, China	ARROW DIAGNOSTICS SRL, Italia	arrowdiagnostics@pec.it	COVID-19 IGG LATERAL FLOW ASSAY KIT 40 TEST/COVGLFA-01	---	IT - ITALIA
22	GENOBIO PHARMACEUTICAL CO, LTD, China	ARROW DIAGNOSTICS SRL, Italia	arrowdiagnostics@pec.it	COVID-19 IGM LATERAL FLOW ASSAY KIT 40 TEST/COVMLFA-01	---	IT – ITALIA
23	CLONIT SRL, Italia	NA	INFO@PEC.CLONIT.IT	QUANTY COVID-19	---	IT – ITALIA
24	OACP S.R.L., Italia	NA	OACP@PEC.IT	CORONA VIRUS DISEASE 2019 (COVID-19) NUCLEIC ACID DETECTION KIT	---	IT – ITALIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
25	A & B PROFESSIONAL INTERNATIONAL SRL, Italia	NA	AEBPROFESSIONAL.INTERNATIONAL@PEC.IT	A&B RAPID TEST | COVID-19 IGG/IGM CASSETTA	---	IT – ITALIA
26	DIASORIN MOLECULAR LLC, SUA	DIASORIN S.P.A., Italia	gestioneofferte.pec@legal.diasorin.it	SIMPLEXA# COVID-19 POSITIVE CONTROL PACK	---	IT – ITALIA
27	DIASORIN MOLECULAR LLC, SUA	DIASORIN S.P.A., Italia	gestioneofferte.pec@legal.diasorin.it	SIMPLEXA COVID-19 DIRECT	---	IT – ITALIA
28	ALCO-SERVICE DI CRIPPA ANDREA CRISTIAN, Italia	NA	info@alco-service.it	TEST COVID-19 - 2019-NCOV IGG/IGM RAPID TEST CASSETTE SINGLE USE KIT	---	IT – ITALIA
29	SENTINEL CH. SPA, Italia	NA	sentinel@sentinel.it	STAT-NAT COVID-19 B	---	IT – ITALIA
30	SENTINEL CH. SPA, Italia	NA	sentinel@sentinel.it	STAT-NAT COVID-19 HK	---	IT – ITALIA
31	SCREEN ITALIA SRL, Italia	NA	info@screenitalia.it	SCREEN TEST COVID-19 -COVID-19 IGG/IGM RAPID TEST DIPSTICK	---	IT – ITALIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
32	AITbiotech Pte. Ltd., Singapore	Emergo Europe B.V., Olanda	Prinsessegracht 2514 AP 's-Gravenhage Netherlands	abTES COVID-19 qPCR I Kit	The abTES™ COVID-19 qPCR I Kit is a qualitative real-time polymerase chain reaction (qPCR) kit which enables simultaneous detection of two COVID-19- specific signature regions from its non-structure polypeptide in a single reaction. The kit contains all the necessary PCR reagents for rapid, sensitive and specific detection using target-specific primers and double-labeled hydrolysis probes. The RNA should be extracted and purified from respiratory specimens including nasopharyngeal wash or aspirate, nasal aspirate, nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage, tracheal aspirate, sputum and serum, as recommended by CDC2. The abTES™ COVID-19 qPCR I Kit enables detection of human housekeeping gene,GAPDH, as an Internal Control (IC) to identify possible PCR inhibitions from sample processing.	NL - OLANDA
33	Chaozhou Hybribio Biochemistry, China	Emergo Europe B.V., Olanda	Prinsessegracht 2514 AP 's-Gravenhage Netherlands	HBRT-COVID-19	The COVID-19 Real-time PCR Kit (HBRT-COVID-19) is designed for in vitro detection of any suspected infection by novel coronavirus that may induce severe coronavirus pneumonia (CNP) by using the targeting genes of ORFlab and N targeting genes, with B2M gene as internal control	NL – OLANDA
34	GenSure Biotech Inc., China	QualRep Services B.V., Olanda	Utrechtseweg 6812 AR Arnhem Netherlands	GenSureTM COVID-19 IgG/IgM Rapid Test	This product is used for the qualitative testing of new coronavirus SRAS-CoV-2 IgG/IgM antibodies in human serum, plasma or whole blood.	NL – OLANDA
35	GenSure Biotech Inc., China	QualRep Services B.V., Olanda	Utrechtseweg 6812 AR Arnhem Netherlands	GenSureTM COVID-19 IgM Rapid Test	This product is used for the qualitative testing of new coronavirus SRAS-CoV-2 IgM antibodies in human serum, plasma or whole blood.	NL – OLANDA
36	Life Technologies Corporation, SUA	Life Technologies Europe B.V., Olanda	Kwartsweg 2665 NN Bleiswijk Netherlands	TaqPath™ COVID-19 CE-IVD RT-PCR Kit	TaqPath™ COVID-19 CE-IVD RT-PCR Kit contains the reagents and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19.	NL – OLANDA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
37	Autobio Diagnostics Co. Ltd, China	OBELIS S.A., Belgia	mail@obelis.net	SARS-CoV-2 lgG CLIA Microparticles	SARS-CoV-2 lgG CLIA Microparticles is an assay based on a chemiluminescent microparticle Immunoassay (CLIA Microparticles) for the qualitative detection of SARS-CoV-2 lgG (lgG antibodies to Severe Acute Respiratory Syndrome Coronavirus 2) in human serum and plasma	BE – BELGIA
38	Autobio Diagnostics Co. Ltd, China	OBELIS S.A., Belgia	mail@obelis.net	SARS-CoV-2 lgM CLIA Microparticles	SARS-CoV-2 lgM CLIA Microparticles is an assay based on a chemiluminescent microparticle Immunoassay (CLIA Microparticles) for the qualitalive detection of SARS-CoV-2 IgM (lgM antibodies to Severe Acute Respiratory Syndrome Coronavirus 2) in human serum and plasma	BE – BELGIA
39	GUANGZHOU WONDFO BIOTECH CO. LTD, China	MINIAS GLOBE DIAGNOSTICS S.R.L., Italia	miniasglobediagnostics@pec.it	SARS-COV-2 ANTIBODY TEST	---	IT – ITALIA
40	GUANGZHOU WONDFO BIOTECH CO. LTD, China	MINIAS GLOBE DIAGNOSTICS S.R.L., Italia	miniasglobediagnostics@pec.it	SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)	---	IT – ITALIA
41	GUANGZHOU WONDFO BIOTECH CO. LTD, China	MINIAS GLOBE DIAGNOSTICS S.R.L., Italia	miniasglobediagnostics@pec.it	SARS-COV-2 IGM TEST	---	IT – ITALIA
42	Suzhou Sym-Bio Lifescience Co., Ltd, China	Emergo Europe B.V., Olanda	Prinsessegracht 2514 AP 's-Gravenhage Netherlands	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay is used for the detection of SARS-CoV-2 RNA in human oropharyngeal swab, nasopharyngeal swab, bronchoalveolar lavage (BAL), sputum, plasma or serum. Coronavirus disease 2019 (COVID-19) is one respiratory disease caused by a novel coronavirus named "SARS-CoV-2", the virus was first detected in China and now has been detected in almost 70 locations internationally. SARS-CoV-2 RNA, as an effective marker, has been widely used in clinical diagnosis and treatment.	NL – OLANDA
43	Biotech & Biomedicine (Shenyang) Group Ltd., China	OBELIS S.A., Belgia	mail@obelis.net	Real Time PCR Detection Kit For COVID-19 Coronavirus	Real Time PCR Detection Kit For COVID-19 Coronavirus is used for the relative quantitative detection of SARS-CoV-2	BE – BELGIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
44	Biotech & Biomedicine (Shenyang) Group Ltd., China	OBELIS S.A., Belgia	mail@obelis.net	Colorimetric And Isothermal Detection Kit For COVID-19 Coronavirus	---	BE – BELGIA
45	Philosys Co Ltd., Coreea	OBELIS S.A., Belgia	mail@obelis.net	Gmate® COVID-19	---	BE – BELGIA
46	Osang Healthcare Co., Ltd, Coreea	OBELIS S.A., Belgia	mail@obelis.net	Gene Finder Covid-19 Plus Real Amp Kit	Real time PCR assay for covid-19	BE – BELGIA
47	Bioneer Corporation, Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	AccuPower BKV Quantitative PCR Kit; AccuPower Norovirus Real-Time RT-PCR Kit; AccuPower STI 8B-Plex Real-Time PCR Kit; AccuPower® MERS-CoV (upE&ORF1a) Real-Time RT-PCR Kit; AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit; AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit; AccuPower® COVID-19 Real-Time RT-PCR Kit	Different Real time PCR kits for the detection of different virology pathogens in human clinical samples. For professional use. Internal Admin.-No.: BION-11, BION-11-01, BION-11-02, BION-11-04, BION-11-05; BION-11-06; BION-11-07	DE – GERMANIA
48	AccuBioTech Co., Ltd., China	Medical Device Safety Service GmbH, Germania	anzeigen@mdssar.com	Accu-Tell® Rapid Chikungunya IgG/IgM Test; Accu-Tell® Rotavirus Test; Accu-Tell® Rotavirus/Adenovirus Test; Accu-Tell® Norovirus Test; ACCU-TELL® COVID-19 IgG/IgM Cassette	15 70 90 90 - Other Other Virology RT & POC	DE – GERMANIA
49	GenBody Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	GenBody YFV IgG/IgM DUO; GenBody Chikungunya IgM; GenBody ZIKA IgG/IgM; GenBody ZIKA NS1 Ag; GenBody YFV IgG/IgM; GenBody YFV NS1 Ag; GenBody COVID-19 IgM/IgG	Various chromatographic immunoassays and rapid qualitative tests for the detection of different immunoglobulin G, immunoglobulin M and NS1 antigens in human blood (serum, plasma and whole blood). For professional use only. Internal Admin-No.: GEB-08, GEB-08-01 to GEB-08-06.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
50	SD Biosensor, Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	STANDARD# Influenza A/B Control, STANDARD# Strep A Ag Control, STANDARD# Legionella Ag Control, STANDARD# S.pneumoniae Ag Control, STANDARD# RSV Ag Control; STANDARD# Dengue NS1 Ag control; STANDARD#Q COVID-19 Ag Control; STANDARD# COVID 19 IgM/IgG Control	Various controls intended for use as an external quality control material to monitor the performance of different test kits. It is important to perform control tests with positive and negative control materials to assure your system is working properly. Internal Admin-No.: SDB-55, SDB-55-01 to SDB-55-07.	DE – GERMANIA
51	GeneMatrix Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	NeoPlex# GI-Virus 6 Detection Kit; NeoPlex# COVID-19 Detection Kit	The 'NeoPlex # GI-Virus 6 Detection Kit' is a qualitative in vitro test for the simultaneous detection of six gastrointestinal infection(GI) causing pathogens including Norovirus GI(NoV GI), Norovirus GII(NoV GII), Astrovirus(AsV) and Sapovirus(SaV) [Rotavirus A(RoV) and Adenovirus F (AdV) seperatly notifed] from stool specimen using one step based multiplex real time RT PCR. The 'NeoPlex# COVID-19 Detection Kit' Assay is a qualitative in vitro test for the simultaneous detection and confirmation of N gene and RdRp gene in 2019-novel Coronavirus causing COVID-19 from Respiratory specimens (Sputum, Bronchoalveolar lavage fluid (BAL), Nasopharyngeal or Oropharyngeal swab) based on real-time reverse transcription polymerase chain reaction(RT-PCR) assay. For professional use only. Internal Admin-No.: HBI-17+HBI-17-01.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
52	Wuhan HealthCare Biotechnology Co., Ltd, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	Corona Virus Disease 2019 (COVID-19) Nucleic Acid Detection Kit	The novel coronavirus ORF 1ab and the conserved region encoding nucleocapsid protein N gene sequence were designed by GISAID kit. Two pairs of specific primers and Taqman probes were designed. The virus nucleic acids in the samples were qualitatively analyzed by one-step fluorescence PCR detection. It is used for in vitro qualitative detection of nasopharyngeal swab, sputum and bronchoalveolar lavage fluid samples, orf1ab and N genes of new coronavirus in patients with suspected new coronavirus infection pneumonia, suspected clustered pneumonia and other patients who need to be diagnosed or differentiated for new coronavirus infection.	DE – GERMANIA
53	1drop Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	1copy# COVID-19 qPCR Kit; 1copy# COVID-19 qPCR Multi Kit	The 1copy# COVID-19 qPCR Kit is used for qualitative analysis of E gene and RdRp gene for coronavirus (COVID-19) in extracted RNA from sputum, nasopharyngeal swab and oropharyngeal swab of patients with suspected respiratory infections. The 1copy# COVID-19 qPCR Multi Kit is an in vitro real-time RT-PCR test for qualitative detection of the E gene and RdRp gene of SARS-CoV-2 extracted RNA from nasopharyngeal swab and oropharyngeal swab from individuals with signs and symptoms of infection who are suspected of COVID-19. For professional use only. Internal Admin-No.: DRO-10, DRO-10-01.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
54	SD Biosensor, Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	STANDARD# M nCoV Real-Time Detection kit; STANDARD# F COVID-19 Ag FIA; STANDARD# F COVID 19 IgM/IgG Duo FIA	STANDARD# M nCoV Real-Time Detection kit is used for identification and detection of novel coronavirus (2019-nCoV) nucleic acids (NA) in human nasopharyngeal swab, oropharyngeal swab, sputum, and bronchoalveolar lavage fluid (BALF) specimens using reverse transcription (RT) real-time PCR. STANDARD F COVID-19 Ag FIA is the fluorescent immunoassay to detect COVID-19 infection in human nasopharyngeal swab specimen, identifying existence of COVID-19 viral nucleoprotein antigens. STANDARD F COVID-19 IgM/IgG Duo FIA is the fluorescent immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum and whole blood. For professional use only. Internal Admin-No.: SDB-68, SDB-68-01, SDB-68-02.	DE – GERMANIA
55	Sugentech, Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	SGTi-flex COVID-19 IgG; SGTi-flex COVID-19 IgM; SGTi-flex COVID-19 IgM/IgG	Immunoassay tests for the qualitative detection of IgG and IgM antibodies to Covid-19 in human Serum/Plasma. The test is useful as a screening test for COVID-19 viral infection. For professional use only. Internal Admin-No.: SUG-19; SUG-19-01, SUG-19-02.	DE – GERMANIA
56	KH Medical Co., Ltd., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	RADI COVID-19 Detection Kit	The RADI COVID-19 Detection Kit is an in vitro diagnostic medical device, based on realtime RT-PCR technology utilizing reverse-transcriptase (RT) reaction to convert RNA into complementary DNA (cDNA). It is intended for the presumptive qualitative detection of nucleic acid from the COVID-19 in upper and lower respiratory specimens. The assay is for use by a laboratory professional trained to use real-time PCR in a laboratory. Internal Admin.-No.:KHM-01.	DE GERMANIA
57	CTK Biotech Inc., SUA	Medical Device Safety Service GmbH, Germania	anzeigen@mdssar.com	OnSite COVID-19 IgG/IgM Rapid Test; Aria COVID-19 IgG/IgM Rapid Test	15 04 80 19 - Coronavirus (EDMA 2019)	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
58	MABSKY BIO-TECH CO.,LTD, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	Influenza A virus; Influenza B virus&COVID-19 virus(2019-nCoV) Triple-Detection Kit (Real-Time PCR Method)	The kit is used for the qualitative detection of COVID-19 virus (2019-nCoV) #Influenza A and Influenza B virus in nasal swab and throat swab specimens. Specific primers and probes are designed according to the highly conserved sequence of Influenza A and Influenza B viruses published on NCBI, and the conserved regions of ORF1ab gene of the COVID-19 virus (2019-nCoV) which recently announced on the GISAID, and a pair of primers and probe of Human internal reference gene (RNP) are used as quality control of sampling, RNA extraction and real-time PCR. The nucleic acid of sample in the specimens is qualitatively analyzed by using one-step fluorescent real-time PCR detection technology after RNA extraction.	DE – GERMANIA
59	MABSKY BIO-TECH CO.,LTD, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	COVID-19 virus(2019-nCoV) Triple-Detection Kit (Real-Time PCR Method)	The kit is used for the qualitative detection of COVID-19 virus (2019-nCoV) in specimens of nasal swab and throat swab, stool or anal swab, blood or serum. The kit designs pairs of specific primers and Taqman probes for the conserved regions of the COVID-19 virus (2019-nCoV) N gene# ORF1ab gene and S gene sequence which recently announced on the GISAID, and a pair of primers and probe of Human internal reference gene (RNP) are used as quality control of sampling, RNA extraction and real-time PCR. The 2019-nCoV nucleic acid in the specimens is qualitatively analyzed by using one-step fluorescent PCR detection technology after RNA extraction	DE – GERMANIA
60	MABSKY BIO-TECH CO.,LTD, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	COVID-19 virus(2019-nCoV) Dual-Detection Kit (Real-Time PCR Method)	The kit is used for the qualitative detection of COVID-19 virus (2019-nCoV) in specimens of nasal swab and throat swab, stool or anal swab, blood or serum. The kit designs pairs of specific primers and Taqman probes for the conserved regions of the COVID-19 virus (2019-nCoV) N gene and ORF1ab gene sequence which recently announced on the GISAID, and a pair of primers and probe of Human internal reference gene (RNP) are used as quality control of sampling, RNA extraction and real-time PCR. The 2019-nCoV nucleic acid in the specimens is qualitatively analyzed by using one-step fluorescent PCR detection technology after RNA extraction.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
61	BioMedomics, Inc., SUA	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	COVID-19 IgM-IgG Rapid Test	Rapid IgM-IgG Combined Antibody Test for COVID-19 is used to qualitatively detect IgG and IgM antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro. Internal Ref No: BIM-03.	DE – GERMANIA
62	Beijing Hotgen Biotech Co., Ltd, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	Coronavirus disease (COVID-19) IgM/IgG Antibody Test (Up-converting Phosphor Technology)	This kit is based on up-converting phosphor technology and uses dual-antigen sandwich method to detect novel coronavirus (COVID-19) IgM /IgG antibodies in blood samples. The detection line (T line) of the new coronavirus (COVID-19) IgM / IgG antibody test card was coated with COVID-19 recombinant antigen, and the quality control line (C line) was coated with goat polyclonal IgG. During the test, the specimen is dropped into the test card and the liquid is chromatographed upward under the capillary effect. The new coronavirus (COVID-19) IgM / IgG antibody in the specimen is first bound to the UCP-labeled COVID-19 recombinant antigen. A solid-phase COVID-19 antigen-COVID-19 IgM / IgG antibody-labeled COVID-19 recombinant antigen-UCP particle complex was formed at the T-line position, and a solid-phase sheep polyclonal IgG-labeled COVID-19 recombinant antigen UCP particle complex was formed at the C-line position. UCP particles emit visible light signals under excitation light. The ratio of the T-line and C-line signals (T / C) is directly proportional to the concentration of the new coronavirus (COVID-19) antibody in the sample. When using with the up-converting phosphor immunoassay analyzer, the detection signal value of the new coronavirus (COVID-19) antibody in the sample can be directly read from the screen of the analyzer, and the detection result can be judged by the signal value.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
63	Beijing Hotgen Biotech Co., Ltd, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold)	This kit is based on the colloidal gold immunochromatographic technology, and uses double antigen sandwich method to detect the novel coronavirus IgM / IgG antibody in blood samples. The detection line (T line) of the novel coronavirus IgM / IgG antibody test cassette was coated with CoV recombinant antigen, and the quality control line (C line) was coated with goat polyclonal IgG. During the test, the sample is dropped into the test cassette and the liquid is chromatographed upward under the capillary effect. The novel coronavirus IgM / IgG antibody in the sample first binds to the colloidal gold-labelled CoV recombinant antigen to form a solid phase CoV antigen-CoV IgM / IgG antibody-labelled CoV recombinant antigen-colloidal gold complex, at the C line position form a solid phase goat polyclonal IgG-labelled CoV recombinant antigen-colloidal gold complex; after the test is completed, observe the Colloidal gold color reaction of T line and C line to determine results of novel coronavirus IgM / IgG antibodies in blood samples.	DE – GERMANIA
64	CANKADO Service GmbH, Germania	NA	m.mika@cankado.com	CANKADO COVID-19 Caregiver Cockpit	The CANKADO COVID-19 Caregiver Cockpit is for medical personnel who care for COVID-19 patients. COVID-19 patients, who are fit enough to use their Smartphone according to the assessment of the caring institution, document their body temperature and oxygen saturation independently by means of Smartphone-APP. This information is displayed cumulated in real time in the COVID-19 web portal within CANKADO for the medical staff. The tool is suitable for stationary and ambulant patients.	DE – GERMANIA
65	Genomictree, Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	AccuraTect# COVID-19 RT-qPCR Kit V1	AccuraTect# COVID-19 RT-qPCR Kit V1 is the RT-qPCR assays for in vitro qualitative detection of genes (E, RdRp and N) of novel corona virus (SARS-CoV-2) from the sample (Sputum, oropharyngeal and nasopharyngeal swab) of respiratory infectious suspected patient. For professional use only. Internal Admin-No.: GEO-02.	DE - GERMANIA
66	Humasis Co., Ltd., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	Humasis COVID-19 IgG/IgM Test	Humasis COVID-19 IgG/IgM test is one step in vitro diagnostic test based on an immunochromatographic assay. It is designed for qualitative detection of Immunoglobulin G and Immunoglobulin M antibody of Novel Coronavirus (COVID-19) in human blood. For professional use only. Internal Admin-No.: HUM-18	DE - GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
67	PaxGenBio Co., Ltd., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	PaxView COVID-19 real-time RT-PCR Kit	PaxView® COVID-19 real-time RT-PCR Kit is designed for the qualitative detection of COVID-19 viral RNA in oropharyngeal swab, nasopharyngeal swab, sputum and bronchoalveolar lavage (BAL). For professional use only. Internal Admin-No.:PAX-03.	DE – GERMANIA
68	NanoEnTek Inc., Coreea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	FREND# COVID-19 IgG/IgM Duo	FREND# COVID-19 IgG/IgM Duo is designed for the qualitative measurement of anti-coronavirus IgG and IgM in human serum and plasma (Li-heparinized, K3-EDTA, and citrate) by fluorescence immunoassay (FIA) using the FREND# System. FREND # COVID-19 is an in vitro diagnostic medical device that helps identify coronavirus disease 2019 (COVID-19) infections. Internal Admin.-Nr.: NET-32.	DE – GERMANIA
69	CTK Biotech Inc., SUA	Medical Device Safety Service GmbH, Germania	anzeigen@mdssar.com	Aridia COVID-19 Real-Time PCR Test	EDMA (2019): 15 04 40 19 - Coronavirus - NA Reagents	DE – GERMANIA
70	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD., China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	COVID-19(SARS-CoV-2) Antibody Test Kit(Colloidal Gold)	COVID-19#SARS-CoV-2#IgG/IgM Test is the colloidal gold labeled rabbit IgG and the novel coronavirus (COVID-19) antigen, while the nitrocellulose membrane is coated with anti-human IgG and IgM and sheep anti-rabbit IgG combined to form a band. The principle of colloidal gold immunochromatography indirect method is used to detect the novel coronavirus (COVID-19) IgG/IgM antibody in human serum.	DE - GERMANIA
71	Shaanxi Lifegen. Co., Ltd., China	Osmunda Medical Technology Service GmbH, Germania	eu@osmundacn.com	Novel coronavirus (COVID-19) nucleic acid detection kit	Novel coronavirus (2019-nCoV) can cause symptoms such as viral pneumonia and dyspnea. This kit is intended to be used for nucleic acid detection of novel coronavirus 2019 nCoV, and the results can be used for auxiliary diagnosis of patients infected with 2019 nCoV or suspected 2019-nCoV patients, thus providing molecular diagnosis basis for infected patients. The test results obtained through this kit are for clinical reference only and cannot be considered as the only basis for clinical diagnosis. It is suggested that the clinical manifestations of patients and other laboratory test methods be combined to make a comprehensive analysis of the condition of disease.	DE - GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
72	Beijing Hotgen Biotech Co., Ltd, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	Coronavirus disease (COVID-19) Antibody Test (Enzyme-Linked Immunosorbent Assay)	This kit is based on enzyme-linked immunosorbent assay (ELISA) and uses dual antigen sandwich method to detect novel coronavirus (COVID-19) antibodies in blood samples. First, the recombinant antigen of the novel new coronavirus (COVID-19) is coated on the microtiter plates, which can be combined with the novel coronavirusnew coronavirus (COVID-19) antibody (tested antibody) in the sample, and added with the HRP-labelled novel coronavirus (COVID-19). recombinant antigen to form an immune complex with a "recombinant antigen-test antibody-recombinant antigen-HRP" structure. After washing with thea washing solution, adding chromogena coloring solution is added to there will generate a blue product substrance under at the catalysis of the enzyme. After stopping the enzyme reaction with stop solution. After the enzyme reaction, the solution in the microwells turns yellow, and the intensity of the color is proportional to the concentration of the test antibody in the sample within a certain range.	DE - GERMANIA
73	Biomerica, Inc., SUA	Medical Device Safety Service GmbH, Germania	anzeigen@mdssar.com	COVID-19 IgG/IgM Rapid Test	15 70 90 90 - Other Other Virology - RT & POC (EDMA 2019)	DE – GERMANIA
74	Beijing Hotgen Biotech Co., Ltd, China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	Coronavirus disease (COVID-19) Nucleic Acid Test Kit (PCR-Fluorescent Probe Method)	The kit (PCR-fluorescent probe method) is used to detect the ORF1ab gene, N gene and S gene of the new coronavirus (COVID-19). The detection reagent contains a reverse transcription primer, ORF1ab gene, N gene and S gene specific amplification primers and corresponding fluorescent probes, which are formulated into RT-PCR reaction solution together with RT-PCR reaction buffer, Taq enzyme, reverse transcriptase, etc. one-step RT-PCR amplification on a real-time quantitative PCR instrument achieves the qualitative detection of ORF1ab gene, N and S genes of the new coronavirus (COVID-19) in nasal, throat swabs, sputum, and alveolar lavage fluid. This kit contains internal standard substances for quality control of nucleic acid extraction and amplification processes.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
75	BeiJing Abace Biology Co., Ltd., China	Luxus Lebenswelt GmbH, Germania	info.m@luxuslw.de	COVID-19 IgM/IgG Antibody Test Kit (Colloidal Gold Immunochromatography)	This kit uses immunochromatography. The test card contains: 1) colloidal gold-labeled recombinant new coronavirus antigen and quality control antibody gold markers; 2) two test lines (G and M lines) and one quality Control line (C line) coated on nitrocellulose membrane. The M line is immobilized with a monoclonal anti-human IgM antibody for detecting a new coronavirus IgM antibody; the G line is immobilized with a reagent for detecting a new coronavirus IgG antibody; and the C line is immobilized with a quality control antibody. When an appropriate amount of the test sample is added to the sample hole of the test card, the sample will move forward along the test card under the action of the capillary. If the sample contains an IgM antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen. The immune complex will be captured by the anti-human IgM antibody immobilized on the membrane to form a purple-red M line, showing that the new coronavirus IgM antibody is positive. If the sample contains an IgG antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen, and the immune complex will be captured by the reagent immobilized on the membrane to form a purple-red G line, indicating that the new coronavirus IgG antibody is positive. If the test lines G and M are not colored, a negative result is displayed. The test card also contains a quality control line C. The fuchsia quality control line C should appear regardless of whether a test line appears. The quality control line is a color band of the quality control antibody immune complex. If the quality control line C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
76	Chongqing Western Biomedical Technology Co,Ltd., China	Share Info Consultant Service LLC Repräsentanzbüro , Germania	eu-rep@share-info.cn	Nucleic Acid Detection Kit for Novel Coronavirus (COVID-19) One-Step Taqman qPCR	This kit is used for nucleic acid detection of novel coronavirus (COVID-19). The results can be used for auxiliary diagnosis of novel coronavirus infected patients or suspected patients, and provide molecular diagnostic basis for infected patients. The test results of this kit are only for clinical reference and should not be used as the only standard for clinical diagnosis. It is suggested to make a comprehensive analysis of the patient's condition combined with manifestations and other laboratory tests.	DE – GERMANIA
77	Epitope Diagnostics, Inc., SUA	Medical Device Safety Service GmbH, Germania	anzeigen@mdssar.com	EDI# Novel Coronavirus COVID-19 IgG ELISA Kit; EDI# Novel Coronavirus COVID-19 IgM ELISA Kit	15 04 80 19 - Coronavirus (EDMA 2019)	DE - GERMANIA
78	DIATHEVA S.R.L., Italia	NA	diathevasrl@legalmail.it	COVID-19 PCR DIATHEVA DETECTION KIT	---	IT – ITALIA
79	ERGON SUTRAMED S.R.L., Italia	NA	VIA G. GREGORACI, 12 ROMA,00173, Italy	COVID-19 IGG/IGM RAPID TEST CASSETTE	---	IT – ITALIA
80	BOSTON BIO LAB INC., SUA	Green Label Manufacturing SIA, Letonia	greenlabelcorp@gmail.com	COVID-19 Home Test Kit for detection of IgM antibody of SARS-CoV-2	Set of reagents and other related materials used to quantify and/or qualitatively detect IgM antibodies against SARS-CoV-2 in a clinical sample using the EIA method	LT – LETONIA
81	Nantong Egens Biotechnology Co., Ltd, China	Shanghai International Holding Corporation GmbH (Europe), Germania	shholding@hotmail.com	COVID-19 IgG/IgM Rapid Test Kit	COVID-19 IgG/IgM Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary SARS-COV-2 infections.	DE – GERMANIA

TABEL / 20.04.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO (TESTE) INREGISTRATE IN UNIUNEA EUROPEANA

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
82	Core Technology Co.,Ltd., China	Wellkang Ltd., UK	16 Castle Street, CT16 1PW Dover, UK	COVID-19 IgM/IgG Ab Test	---	UK – MAREA BRITANIE
83	SureScreen Diagnostics, UK	NA	1 Prime Parkway, Derby, UK	COVID-19 IgG/IgM Rapid Test Cassete (Whole Blood / Serum / Plasma)	---	UK – MAREA BRITANIE
84	Healgen Scientific Limited Liability Company, SUA	Shanghai International Holding Corporation GmbH (Europe), Germania	shholding@hotmail.com	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) – marca Healgen	The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood / Serum / Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma and provides only a preliminary test result, therefore any reactive specimen with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.	DE – GERMANIA
85	Changsha Sinocare Inc., China	Shanghai International Holding Corporation GmbH (Europe), Germania	shholding@hotmail.com	SARS-CoV-2 IgG Antibody Test Strip – marca SINOCARE	SARS-CoV-2 IgG Antibody Test Strip is for the qualitative detection of SARS-CoV-2 IgG antibody in human serum, plasma or whole blood sample. It is intended for use outside the body only (in vitro diagnostic use) for professional use.	DE – GERMANIA
86	Changsha Sinocare Inc., China	Shanghai International Holding Corporation GmbH (Europe), Germania	shholding@hotmail.com	SARS-CoV-2 IgM Antibody Test Strip – marca SINOCARE	SARS-CoV-2 IgM Antibody Test Strip is for the qualitative detection of SARS-CoV-2 IgM antibody in human serum, plasma or whole blood sample. It is intended for use outside the body only(in vitro diagnostic use)for professional use.	DE – GERMANIA
87	Changsha Sinocare Inc., China	Shanghai International Holding Corporation GmbH (Europe), Germania	shholding@hotmail.com	SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method) – marca SINOCARE	SARS-CoV-2 Antibody Test Strip(Colloidal Gold Method) is for the qualitative detection of SARS-CoV-2 antibody in human serum, plasma or whole blood sample. It is intended for use outside the body only（in vitro diagnostic use） for professional use.	DE – GERMANIA