

ORDER

РД-01-977/26.11.2021 Document Registered by

Pursuant to Art. 61, para. 2, Art. 63, para. 4, 5 and 11 and Art. 63c of the Health Act, Art. 73 of the Code of Administrative Procedure, and in relation to Regulation (EU) 2021/953 of the European Parliament and of the Council dated 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable vaccination certificates against, COVID testing and recovery -19 (EU Digital COVID certificate) in order to facilitate free movement during the COVID-19 pandemic and Council of Ministers Decision № 826 dated 25 November 2021 extending the term announced by Council of Ministers Decision № 325 dated 14 May 2020 extraordinary epidemic situation, extended by Decision № 378 of the Council of Ministers dated 12 June 2020, Decision № 418 dated the Council of Ministers dated 25 June 2020, Decision № 482 of the Council of Ministers dated 15 July 2020, Decision № 525 of the Council of Ministers dated 30 July 2020, Decision № 609 of the Council of Ministers dated 23 August 2020, Decision № 673 of the Council of Ministers dated 25 September 2020, Decision № 855 of the Council of Ministers dated 25 November 2020, Decision № 72 of the Council of Ministers dated 26 January 2021, Decision № 395 of the Council of Ministers dated 28 April 2021, Decision № 426 of the Council of Ministers dated 26 May 2021, Decision № 547 of the Council of Ministers dated 28 July 2021 and Decision № 629 of the Council of Ministers dated 26 August 2021 and a proposal by the Chief State Health Inspector

ORDER:

I. I introduce the following temporary control measures regarding the entry of persons arriving from other countries on the territory of the Republic of Bulgaria, as of 1.12.2021 to 31.03.2022, according to an assessment of the spread of COVID-19 in the respective country according to criteria and placing the countries in color zones as follows:

1. Criteria for assessing the prevalence of COVID-19 in the country concerned:

1.1. 14-day incidence rate - the total number of newly registered cases of COVID-19 in the last 14 days per 100,000 population in the respective country;

1.2. weekly positivity of the performed laboratory tests - relative share in % of the positive samples in the country in relation to all performed PCR tests and rapid antigenic tests for SARS-CoV-2 infection during the last week (last 7 days);

1.3. level of testing in the country - number of tests performed for SARS-CoV-2 infection per 100,000 population in the last week (last 7 days);

1.4. identification of a variant of SARS-CoV-2 identified as a concern;

1.5. lack of sufficient information, periodic updating of information or a reliable source of information about a country.

2. Color zones:

2.1. Green zone:

2.1.1. if at the time of assessment, the 14-day incidence rate per 100,000 population is lower than 75 per 100,000 population; or

2.1.2. if at the time of assessment the 14-day incidence rate per 100,000 population is between 75 and 200 per 100,000 population and the weekly positivity of the laboratory tests performed is less than 4%.

2.2. Orange zone:

2.2.1. if at the time of assessment the 14-day incidence rate per 100,000 population is between 75 and 200 per 100,000 population and the weekly positivity of the laboratory tests performed is higher or equal to 4%; or

2.2.2. if at the time of assessment the 14-day incidence rate per 100,000 population is between 200 and 500 per 100,000 population.

2.3. Red zone:

2.3.1. if, at the time of assessment, the 14-day incidence rate per 100,000 population is higher than or equal to 500 per 100,000 population; or

2.3.2. lack of sufficient information, periodic updating of information or a reliable source of information for the country concerned, or if the level of the survey is lower than 300 samples per 100,000 population; or

2.3.3. if a "variant of concern" of SARS-CoV-2 is spreading in the respective country,

taking into account the sequencing volumes and their level of transmission.

2.4. If there is information about a significant negative change in the epidemic situation in the respective country from a green or orange zone or in some of its territories, before the official change of the color zone of the country with regard to persons arriving in the Republic of Bulgaria, specific control measures may be applied, announced in Annex N_{2} 1.

3. The list of countries by color zones, countries for which a significant negative change in the epidemic situation under item 2.4 has been established, as well as countries with which the Republic of Bulgaria has reached an agreement on a reciprocal basis for free movement of their citizens and persons with the status of permanent, long - term or continuous residence and members of their families, upon arrival from the other country is contained in Annex N_{2} 1.

3.1. The list under item 3 is determined on the basis of information published by the European Center for Disease Prevention and Control (ECDC) - for the Member States of the European Union and the European Economic Area (EU and EEA), the World Health Organization and the Control Center of diseases - Atlanta, USA - for all countries and the spread of "variants of concern".

3.2. All countries, outside the European Union and the European Economic Area and the Swiss Confederation, which do not fall into the red zone, according to the information under item 3.1., are considered to be orange zone countries.

3.3. The list under item 3 is reviewed periodically and, if necessary, updated every 14 days, and in case of deterioration of the epidemic situation in the respective country it can be updated more frequently.

3.4. The information under item 3 is monitored and prepared by the National Center for Infectious and Parasitic Diseases.

4. Temporary anti-epidemic measures for arrivals, according to color zones:

4.1. Green zone - persons are admitted to the territory of the country upon presentation of a valid EU digital COVID certificate for vaccination, recovery or testing or a similar document containing the same data as the EU digital COVID certificate.

4.1.1. Persons who do not present a document under item 4.1 shall be quarantined for 10 days in the home or other place of accommodation in which the person has indicated that he will reside, with a prescription issued by the director of the relevant regional health inspection or by an authorized by him deputy director.

4.1.2. The quarantined person under item 4.1.1. may carry out a polymerase chain reaction test to detect COVID-19 or a rapid antigen test as specified in Annex N_2 2 not earlier than 72 hours of arrival in the country. In case of a negative result from the conducted examination, the quarantine of the person shall be considered terminated from the day following the registration of the result in the National Information System for Combating COVID-19.

4.2. Orange Zone - Persons are admitted to the territory of the country upon presentation of a valid EU digital COVID certificate for vaccination, recovery or testing or a similar document containing the same data as the EU digital COVID certificate.

4.2.1. Persons who do not present a document under item 4.2 shall be placed under quarantine for a period of 10 days in the home or other place of accommodation in which the person has indicated that he will reside, with a prescription issued by the director of the relevant regional health inspectorate or Deputy Director authorized by him.

4.2.2. The quarantined person under item 4.2.1. may carry out a polymerase chain reaction test to detect COVID-19 or a rapid antigen test as specified in Annex N_{2} 2 not earlier than 72 hours of arrival in the country. In case of a negative result from the conducted examination, the quarantine of the person shall be considered terminated from the day following the registration of the result in the National Information System for Combating COVID-19.

4.3. Red zone - on the territory of the country are allowed only persons who are:

4.3.1. bulgarian citizens and persons with the status of permanent, long-term or continuos residence on the territory of the Republic of Bulgaria and members of their families;

4.3.2. citizens of the European Union, the European Economic Area and the Swiss Confederation, the United Kingdom of Great Britain and Northern Ireland, the countries listed in Annex $N_{\mathbb{P}}$ 4 and their family members arriving from a Member State of the European Union, the European Economic Area, the Swiss Confederation, The United Kingdom of Great Britain and Northern Ireland and from a country listed in Annex $N_{\mathbb{P}}$ 4, which citizens have a valid EU digital COVID certificate for vaccination or recovery or for polymerase chain reaction testing for COVID-19 or an equivalent document according to Annex $N_{\mathbb{P}}$. 4;

4.3.3. medical professionals, medical researchers, social workers and their supervisors, when the purpose of the trip is related to the profession they practice;

4.3.4. workers involved in the supply of medicinal products, medical devices and personal protective equipment, medical equipment, including its installation and maintenance;

4.3.5. officials (heads of state, members of governments, etc.) and members of their delegations, as well as diplomats, members of the administrative and technical staff of foreign missions, employees of international organizations, military personnel, members of the security services and public order, and humanitarian workers in the performance of their duties, as well as members of their families;

4.3.6. persons traveling for humanitarian reasons within the meaning of § 1, item 16 of the additional provisions of the Law on Foreigners in the Republic of Bulgaria;

4.3.7. seasonal agricultural workers and workers in the field of tourism;

4.3.8. foreign citizens, for receiving a decree under the Bulgarian Citizenship Act for acquired Bulgarian citizenship, certified by a letter of the Ministry of Justice;

4.3.9. foreign citizens admitted to study in higher educational schools on the territory of the country, certified by a document from the respective higher educational school, except for the

cases under item 5.10, as well as foreign students, other than those specified in item 5.6., holding a type "D" visa residence for educational purposes;

4.3.10. persons other than those specified in items 4.3.1 - 4.3.9., who have received approval from the Minister of Health or a Deputy Minister authorized by him, made on the basis of a motivated written proposal of a Minister, when this is required for particularly important specific reasons. Specific anti-epidemic measures specified in the approval may be laid down for these persons.

4.4. The persons under items 4.3.1 and items 4.3.3 - 4.3.10. are admitted to the territory of the country upon presentation of a valid EU digital COVID certificate for vaccination or for recovery or similar document, or to a negative result from a polymerase chain reaction test for COVID-19 conducted up to 72 hours before entry into the country, certified by a valid EU digital COVID certificate or a similar document containing the same data as the EU digital COVID certificate.

4.5. Bulgarian citizens and persons with the status of permanent, long-term or continuous residence on the territory of the Republic of Bulgaria and members of their families who do not present a document under item 4.4 are allowed on the territory of the country and placed in quarantine for 10 days or in another place of accommodation where the person has indicated that he / she will reside, with a prescription issued by the director of the respective regional health inspection or a deputy director authorized by him.

4.6. Persons arriving from the following countries of the red zone are not allowed on the territory of the country: the Republic of Mozambique, the Republic of Botswana, the Republic of South Africa, Lesotho, Eswatini, the Republic of Namibia and the Republic of Zimbabwe, except for persons who are Bulgarian citizens and persons with status of permanent, long-term or continuous residence on the territory of the Republic of Bulgaria and the members of their families.

4.7. Bulgarian citizens and persons with the status of permanent, long-term or continuous residence on the territory of the Republic of Bulgaria and members of their families arriving from the countries under item 4.6. shall be placed in quarantine for a period of 10 days in the home or other place of accommodation in which the person has indicated that he will reside, with a prescription issued by the director of the respective regional health inspectorate or by a deputy director authorized by him.

4.8. It is obligatory for the persons under item 4.7 to submit by e-mail to the regional health inspectorate, which has placed them under quarantine, a document with a result of a test conducted from the 10th to the 12th day of entry into the country by the method of polymerase chain reaction for proving COVID-19.

5. On the territory of the country are admitted, without the need to present documents for COVID-19, persons arriving from countries other than those under item 4.6., Which are:

5.1. bus drivers and stewards performing international passenger transport;

5.2. truck drivers who perform or complete international transport of stocks and goods upon entering the territory of the Republic of Bulgaria;

5.3. members of the crews of vessels and the persons engaged in the maintenance of the vessels, who upon entering the territory of the Republic of Bulgaria perform their official duties;

5.4. members of the crew of an aircraft that operates flights to and from airports for public use on the territory of the Republic of Bulgaria and the persons engaged in maintenance of aircraft; **5.5**. frontier workers (persons living in the Republic of Bulgaria and traveling daily or at least once a week to a Member State of the European Union, the Republic of Turkey, the Republic of Serbia or the Republic of Northern Macedonia for the purpose of pursuing an employed or self-employed activity, as well as persons who live in the indicated countries and travel daily or at least once a week to the Republic of Bulgaria for the purpose of exercising activity as an employed or as a self-employed person);

5.6. pupils, students and doctoral students living in the Hellenic Republic, the Republic of Turkey, the Republic of Serbia, the Republic of Northern Macedonia and Romania and traveling daily or at least once a week to the Republic of Bulgaria for study purposes, as well as pupils, students and doctoral students living in Republic of Bulgaria and travel daily or at least once a week to the Hellenic Republic, the Republic of Turkey, the Republic of Serbia, the Republic of Northern Macedonia and Romania for educational purposes;

5.7. persons passing in transit through the territory of the Republic of Bulgaria, in the cases when the immediate departure from the territory of the Republic of Bulgaria can be guaranteed;5.8. children up to the age of 12, regardless of the zone in which the country from which they arrive falls in;

5.9. persons arriving from countries with which the Republic of Bulgaria has reached an agreement on a reciprocal basis for free movement of their citizens and persons with the status of permanent, long-term or continuous residence and members of their families, upon arrival from the other country;

5.10. citizens of the Hellenic Republic, Romania, the Republic of Turkey, the Republic of Serbia and the Republic of Northern Macedonia who have been admitted to higher educational schools in the territory of the country, certified by a document from the respective higher educational institution.

6. In case of not less than 5% of the arriving persons under item 4.2. and item 4.3., as well as all persons under item 4.7., a test for COVID-19 is performed with a rapid antigen test by the border health control authorities.

7. Persons, other than those specified in item 5.9, who arrive from a country with which the Republic of Bulgaria has reached an agreement on a reciprocal basis for free passage shall be admitted in accordance with the procedure specified in item 4, according to the color zone of the country.

8. The persons, with the exception of those under item 5, shall be admitted on the territory of the Republic of Bulgaria only through the following border checkpoints (BCPs): Burgas Airport Border Checkpoint; Varna Airport Border Checkpoint; Plovdiv Airport Border Checkpoint; Sofia Airport Border Checkpoint (Terminal 1 and Terminal 2); Border Checkpoint "Port of Burgas"; Port of Varna border checkpoint; Vidin border checkpoint; Vrashka Chuka border checkpoint; Durankulak border checkpoint; Gueshevo border checkpoint; Zlatarevo border checkpoint; Ilinden border checkpoint; Kalotina border checkpoint; Kapitan Andreevo border checkpoint; Captain Petko Voivoda border checkpoint; Kulata border checkpoint; Oltomantsi border checkpoint; Oryahovo border checkpoint; Ruse border checkpoint; Stanke Lisichkovo border checkpoint; Somovit-Nikopol border checkpoint and Strezimirovtsi border checkpoint.

9. The Road Infrastructure Agency shall determine the place where the truck and the driver must stay until the relevant ban is lifted in cases where the drivers of trucks transporting cargo and goods destined for other countries, due to a ban by a border state of the Republic of Bulgaria, cannot leave the country.

10. When establishing a passenger with COVID-19 on board an aircraft that has landed on the territory of the Republic of Bulgaria, the cabin crew members serving the passenger with COVID-19 shall not be planned for the next flight and shall be quarantined for term of 10 days with a prescription issued by the director of the respective regional health inspection or by a deputy director authorized by him.

11. For the purposes of this order:

11.1. "State (territory) from which the person arrives" means the country (territory) - the starting point of his departure, regardless of the stay associated with his transit through other countries during his movement.

11.2. "Valid EU digital COVID vaccination certificate or similar document" is a document for a completed vaccination course against COVID-19. The document must contain the names of the person, written in Latin, according to the identity document with which he travels, date of birth, date on which the last received dose of COVID-19 vaccine was given, serial number of

the dose, and the total number of doses in vaccines to be given twice, the trade name of the vaccine against COVID-19, the name of the manufacturer / holder of the marketing authorization, the country in which it is issued and the name of the issuing competent authority and, for the EU certificate, its unique identifier.

11.2.1. The completion of a vaccination course is considered to be the administration of an appropriate number of doses of a COVID-19 vaccine listed in Annex N_{2} 3 and the expiry of a 14-day period from the date of administration of the last dose. The combination of one dose of Vaxzevria / AZD1222 with one dose of Comirnaty / BNT162b2 (Pfizer-BioNTech Covid-19 vaccine) is also considered a complete vaccination course.

11.3. "Valid EU digital COVID certificate of recovery" is a document certifying that a person has suffered from COVID-19 and which is valid for the period from the 11th to the 180th day from the date of the test entered in the document. The certificate must contain the names of the person written in Latin, according to the identity document with which he travels, date of birth, date of the first positive result of the NAAT test and a positive result (Positive), details of the issuing authority, country, in which the study was done and its unique identifier. "NAAT examination" means a molecular examination for nucleic acid amplification, such as polymerase chain reaction with reverse transcriptase (RT-PCR), cyclic-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques used to detect the presence of ribonucleic acid of SARS-CoV-2 (RNA).

11.3.1. A document similar to the EU digital COVID certificate is a document certifying that a person has recovered from COVID-19, and which is valid for the period from the 11th to the 180th day from the date of the test entered in the document. The document must contain the names of the person, written in Latin, according to the identity document with which he travels, date of birth, date of the first positive result of PCR test or rapid antigen test and positive result (Positive), data about the medical institution, carried out the test (name, address or other contact details) or the issuing authority and the country in which the test was performed.

11.4. "Valid EU COVID digital certificate for testing" or a similar document is a document showing a negative result from a polymerase chain reaction test performed up to 72 hours before entry into the country or a negative result from a rapid antigen test performed up to 48 hours before entry into the country, considered from the date of sampling entered in the document. The document must contain the names of the person written in Latin, according to the identity document with which he travels, date of birth, type of test, written in Latin method (PCR or RAT) and negative result (Negative), date and time of collection of the test sample, trade name and manufacturer of the test (mandatory for rapid antigen tests), name of the laboratory / medical establishment that performed the test, country in which the test was performed and

authority that issued the certificate / document, and for the EU certificate - and its unique identifier.

12. For equal to the EU digital COVID certificates are also considered COVID-19 certificates issued by a third country in accordance with standards and technological systems that are interoperable with the trust framework for EU digital COVID certificate. The list of countries whose COVID-19 vaccination, testing and recovery certificates are considered equivalent to the EU digital COVID certificate is given in Annex N_{2} 4.

II. Order № RD-01-733 dated 27.08.2021, amended by Order № RD-01-767 dated 10.09.2021, Order № RD-01-794 dated 24.09.2021, Order № RD-01- 820 dated 8.10.2021, Order № RD-01-874 dated 26.10.2021 and Order № RD-01-954 dated 19.11.2021 is revoked.

III. The order enters into force on 01.12.2021, with the exception of item 4.6. - 4.8., Which enter into force on 28.11.2021.

IV. The order ought to be published on the website of the Ministry of Health.

The order is subject to appeal within one month from the publication on the website of the Ministry of Health, before the relevant administrative court under the Administrative Procedure Code.

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DR. STOICHO KATSAROV Minister of Health

List of countries by color zones, countries for which there is information about a significant negative change in the epidemic situation and countries with a reciprocal basis

Green zone:

Vatican City State, Kingdom of Spain, Republic of Malta, Kingdom of Sweden.

Orange zone:

All countries outside the green and red zone.

Red zone:

People's Republic of Bangladesh, Myanmar, Kingdom of Bhutan, Democratic Socialist Republic of Sri Lanka, Republic of Maldives, Republic of South Africa, Republic of Botswana, Lesotho, Esvatini, Republic of Zimbabwe, Republic of Mozambique, United Republic of the Republic of Tanzania, Republic of Seychelles, Republic of Namibia, Republic of Zambia, Sultanate of Oman, Turkmenistan, Republic of Tajikistan, Afghanistan, Kyrgyz Republic, Mongolia, Democratic People's Republic of Korea, Republic of Chile, Eastern Republic of Uruguay, Federative Republic of Brazil, Republic of Paraguay, Multinational State of Bolivia, Republic of Suriname, Republic of Panama, Republic of Costa Rica, Republic of Guatemala, Belize, Republic of El Salvador, Republic of Cuba, Dominican Republic, Fiji, Saint Lucia, Federation of Saint Kitts and Nevis, Grenada, Barbados, Singapore, Brunei, United Kingdom of Great Britain and Northern Ireland, Georgia, Montenegro, Republic of Serbia, Republic of Lithuania, Republic of Latvia, the Republic of Estonia, Romania, Slovenia, Croatia, Slovakia Republic, Ukraine, Republic of Austria, Kingdom of the Netherlands, Ireland, Czech Republic, Kingdom of Belgium, Hungary, Kingdom of Denmark, Iceland, Greece, Federal Republic of Germany, Principality of Liechtenstein, Principality of Andorra, Republic of Poland, Confederation of Switzerland, Republic of San Marino, Luxembourg, Kingdom of Norway, the Republic of Cyprus, the Republic of Trinidad and Tobago, the Principality of Monaco. "

Annex № 2 to item I, 4.1.2

Name of the test	Manufacturer	
COVID-VIRO® Rapid antigen test COVID-19	AAZ-LMB	
Panbio [™] COVID-19 Ag Rapid Test	Abbott Rapid Diagnostics	
SARS-CoV-2 Antigen Rapid Test	Acon Biotech (Hangzhou) Co., Ltd	
Flowflex SARS-CoV-2 Antigen Rapid Test	ACON Laboratories, Inc.	
AESKU.RAPID SARS-CoV-2	AESKU.DIAGNOSTICS GmbH & Co, KG	
TestNOW® - COVID-19 Antigen Test	Affimedix Inc.	
AMP Rapid Test SARSCoV-2 Ag	AMEDA Labordiagnostik GmbH	
Rapid COVID-19 Antigen-Test (colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd	
COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Anhui Deep Blue Medical Technology Co., Ltd	
COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal	Anhui Deep Blue Medical Technology Co., Ltd	
Gold) – Nasal swab		
mariPOC SARS-CoV-2	ArcDia International Ltd	
mariPOC Respi+	ArcDia International Oy Ltd	
mariPOC Quick Flu+	ArcDia International Oy Ltd	
Artron COVID-19 Antigen Test	Artron Laboratories Inc.	
Asan Easy Test COVID-19 Ag	Asan Pharmaceutical Co., Ltd	
ECOTEST COVID-19 Antigen Rapid Test Device	Assure Tech. (Hangzhou) Co., Ltd.	
NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	Atlas Link Technology Co. Ltd.	
Ksmart® SARS-COV2 Antigen Rapid Test	Avalun	
COVID-19 Antigen Rapid Test	AXIOM Gesellschaft für Diagnostica und Biochemica mbH	
COVID-19 Antigen Rapid Test Device	Azure Biotech, Inc.	
BD Veritor [™] System for Rapid Detection of SARS- CoV-2	Becton Dickinson	
Novel Coronavirus 2019nCoV Antigen Test (Colloidal Gold)	Beijing Hotgen Biotech Co., Ltd	

Novel Coronavirus (SARSCoV-2) Antigen Rapid Tes Kit	t Beijing Jinwofu Bioengineering Technology Co.,Ltd.	
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd	
Wantai SARS-CoV-2 Ag Rapid Test (FIA)	Beijing Wantai Biological Pharmacy Enterprise Co., Lt	
Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold)	Beijing Wantai Biological Pharmacy Enterprise Co Ltd	
CoviGnost AG Test Device 1x20	BioGnost Ltd	
SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography)	BIOHIT HealthCcare (Hefei) Co., Ltd.	
SARS-CoV-2 Ag Rapid Test	BioMaxima SA	
Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)	Biomerica Inc.	
NowCheck COVID-19 Ag Test	BIONOTE	
CORONAVIRUS AG RAPID TEST CASSETTE	BIO-RAD	
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX S.A.	
BIOSYNEX COVID-19 Ag+ BSS	BIOSYNEX SA	
SARS-CoV-2 Antigen Test Kit (colloidal gold method)	BIOTEKE CORPORATION (WUXI) CO., LTD	
biotical SARS-CoV-2 Ag Card	Biotical Health S.L.U.BIOTICAL HEALTH S.L.U	
AFIAS COVID-19 Ag	Boditech Med Inc	
Rapid Response COVID-19 Antigen Rapid Test	BTNX Inc	
CerTest SARS-CoV-2 Card test	CerTest Biotec	
Coretests COVID-19 Ag Test	Core Technology Co., Ltd	
OnSite COVID-19 Ag Rapid Test	CTK Biotech, Inc	
Test Rapid Covid-19 Antigen (tampon nazofaringian)	DDS DIAGNOSTIC	
DIAQUICK COVID -19 Ag Cassette	DIALAB GmbH	
COVID-19 Antigen Detection Kit	DNA Diagnostic	
Edinburgh Genetics ActivXpress+ COVID-19	Edinburgh Ganatics Limited	
Antigen Complete Testing Kit	Edinburgh Genetics Limited	
EBS SARS-CoV-2 Ag Rapid Test	Eurobio Scientific	
ESPLINE SARS-CoV-2	Fujirebio	
GA CoV-2 Antigen Rapid Test	GA Generic Assays GmbH	
Genbody COVID-19 Ag Test	GenBody Inc	

Genrui Biotech Inc GenSure Biotech Inc	
GenSure Biotech Inc	
Getein Biotech, Inc	
l Getein Biotech, Inc.	
Goldsite Diagnostic Inc.	
Green Cross Medical Science Corp.	
Guangdong Hecin Scientific, Inc.	
Guangdong Longsee Biomedical Co., Ltd.	
Guangdong Wesail Biotech Co. Ltd	
Guangzhou Decheng Biotechnology CO., Ltd	
Guangzhou Wondfo Biotech Co., Ltd	
Hangzhou Lysun Biotechnology Co. Ltd	
Hangzhou AllTest Biotech Co., Ltd	
Hangzhou Clongene Biotech Co., Ltd	
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Hangzhou Immuno Biotech Co., Ltd	
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Hangzhou Testsea Biotechnology Co., Ltd.	
Healgen Scientific	
Hubei Jinjian Biology Co., Ltd	
Humasis	
Jiangsu Bioperfectus Technologies Co., Ltd.	
Jiangsu Diagnostics Biotechnology Co., Ltd	
Jiangsu Medomics medical technology Co.,Ltd.	

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	COVID-19 Antigen Rapid Test Kit (Swab)	Safecare Biotech (Hangzhou) Co. Ltd	

Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	Safecare Biotech (Hangzhou) Co. Ltd	
ScheBo SARS CoV-2 Quick Antigen	ScheBo Biotech AG	
STANDARD Q COVID-19 Ag Test Nasal	SD Biosensor Inc	
STANDARD F COVID-19 Ag FIA	SD BIOSENSOR Inc.	
STANDARD Q COVID-19 Ag Test	SD BIOSENSOR Inc.	
V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)	SGA Medikal	
V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold)	SGA Medikal	
SARS-CoV-2 Antigen Test Kit	Shenzen Ultra-Diagnostics Biotec Co., Ltd	
Green Spring SARS-CoV-2 Antigen-Rapid test-Set	Shenzhen Lvshiyuan Biotechnology Co., Ltd.	
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd	
SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Shenzhen Watmind Medical Co., Ltd	
SARS-CoV-2 Ag Diagnostic Test Kit (Immunofluorescence)	Test Kit Shenzhen Watmind Medical Co., Ltd	
Zhenrui ®COVID-19 Antigen Test Cassette	Shenzhen Zhenrui Biotech Co., Ltd	
CLINITEST Rapid COVID-19 Antigen Test	Siemens Healthineers	
SGTi-flex COVID-19 Ag	Sugentech, Inc.	
TODA CORONADIAG Ag	TODA PHARMA	
SARS-CoV-2 Antigen Rapid Test Kit	Triplex International Biosciences Co., Ltd	
SARS-CoV-2 Antigen Rapid Test Kit	Triplex International Biosciences Co., Ltd, China	
Rapid For SARS-CoV-2 Rapid Ag Test	Vitrosens Biotechnology Co., Ltd	
VivaDiag Pro SARS-CoV-2 Ag Rapid Test	VivaChek Biotech (Hangzhou) Co., Ltd.	
COVID-19 (SARS-CoV-2) Antigen-Test Kit	Wuhan EasyDiagnosis Biomedicine Co., Ltd.	
SARS-CoV-2 Antigen Assay Kit	Wuhan Life Origin Biotech Joint Stock Co., Ltd.	
(Immunochromatography)		
SARS-CoV-2 Antigen Rapid Test Kit	Wuhan UNscience Biotechnology Co., Ltd.	
COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	Xiamen AmonMed Biotechnology Co., Ltd	
Rapid SARS-CoV-2 Antigen Test Card	Xiamen Boson Biotech Co. Ltd	
SARS-CoV-2 Antigen Rapid Test	Xiamen Wiz Biotech Co., Ltd	
SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Xiamen Wiz Biotech Co., Ltd	
AndLucky COVID-19 Antigen Rapid Test	Zhejiang Anji Saianfu Biotech Co, Ltd	

reOpenTest COVID-19 Antigen Rapid Test	Zhejiang Anji Saianfu Biotech Co, Ltd	
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co., Ltd	
COVID-19 Antigen Detection Kit (Colloidal	Zhuhai Lituo Biotechnology Co., Ltd.	
Gold)		

Annex № 3 to item I, 11.2.1

Trade name of the vaccine	Name of the manufacturer / marketing	Completed
according to the EU marketing	cording to the EU marketing authorization holder	
authorization / WHO list		
Comirnaty/ (/ BNT162b2 Pfizer-	BioNTech Manufacturing GmbH/ Pfizer-	2 doses
BioNTech Covid-19 vaccine)	Biontech	
Vaxzevria/ AZD1222	AstraZeneca WCH/ AstraZeneca Canada	2 doses
	Inc.	
- / AZD1222	SK Bioscience Co Ltd	2 doses
Spikevax/COVID-19 VACCINE	MODERNA BIOTECH	2 doses
Moderna / mRNA-1273	MODERNA DIOTECH	
Janssen / Ad26.COV2.S	Janssen-Cilag International NV	1 dose
- / Covishield (ChAdOx1_nCoV-	Serum Institute of India	2 doses
19)	Serum institute of india	
- / SARS-CoV-2 Vaccine (Vero	Sinopharm / BIBP1	2 doses
Cell), Inactivated (InCoV)		
-/ COVID-19 Vaccine (Vero Cell),	Sinovac	2 doses
Inactivated/Coronavac		
- / Sputnik V(Gam-COVID-	The Gamaleya National Center of	2 doses
VacComponent I Gam-COVID-	Epidemiology and Microbiology	
Vac Component II)		
SARS-CoV-2 Vaccine,	Bharat Biotech, India	2 doses
Inactivated (Vero Cell)/		
COVAXIN		

List of countries whose COVID-19 vaccination, testing and disease certificates are considered equivalent to the EU digital COVID certificate

Republic of Northern Macedonia, Republic of San Marino, Swiss Confederation, Republic of Turkey, Ukraine, Vatican City State (only in respect of vaccination certificates issued), Principality of Andorra, Republic of Albania, Faroe Islands, Principality of Monaco, Republic of Panama, Kingdom of Morocco, Israel, Armenia, the United Kingdom of Great Britain and Northern Ireland, the Kingdom of Norway, Iceland, the Principality of Liechtenstein, the Republic of Serbia, the Republic of Singapore, the Togolese Republic, Georgia, the Republic of Moldova and New Zealand.