



REPUBLIC OF BULGARIA

Ministry of Health

Minister of Health

ORDER

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 from 14 June 2021 on a framework for the issuance, verification and acceptance for and recovering from COVID-19 (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic and Council of Ministers Decision № 629 from 26 August 2021 for extending the term of the announced by Council of Ministers Decision № 325 from 14 May 2020 emergency epidemic situation, extended by Decision № 378 of the Council of Ministers from 12 June 2020, Decision № 418 of the Council of Ministers from 25 June 2020, Decision № 482 of the Council of Ministers from 15 July 2020, Decision № 525 of the Council of Ministers from 30 July 2020, Decision № 609 of the Council of Ministers from 23 August 2020, Decision № 673 of the Council of Ministers from 25 September 2020, Decision № 855 of the Council of Ministers from 25 November 2020, Decision № 72 of the Council of Ministers from 26 January 2021, Decision № 395 of the Council of Ministers from 28 April 2021, Decision № 426 of the Council of Ministers from 26 May 2021 and Decision № 547 of the Council of Ministers from 28 July 2021 and a proposal of 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 1.09.2021 to 30.11.2021, 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 spread of COVID-19 in the respective country:

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 conducted laboratory tests - relative share in % of the positive samples in the country in relation to all conducted PCR tests and rapid antigen tests for SARS-CoV-2 infection during the last week (last 7 days);

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

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

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

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 and the weekly positivity of the laboratory tests conducted is higher or equal to 4%; or

2.1.2. if at the time of assessment, 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 conducted 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 conducted 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 on the country, periodic updating of information or a reliable source of information, 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 № 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 the free movement of their citizens and persons with the status of permanent, long-term or continuous residence and their family members, upon arrival from the other country is contained in Annex № 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), by the World Health Organization and the Centers for Disease Control - 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 control measures for arrivals according to color zones:

4.1. Green zone - allowed on the territory of the country upon presentation of a valid EU digital COVID certificate for vaccination, for recovery from the illness or for conducted testing, or of a similar document containing the same data as the EU digital COVID certificate, such as:

4.1.1. in the absence of a valid EU digital COVID certificate or of a similar document containing the same data as the EU digital COVID certificate, the person shall be quarantined for 10 days at home or in another place of accommodation where he/she has indicated that he/she will reside, with a recommendation issued by the Director of the respective Regional Health Inspectorate or a Deputy Director authorized by him;

4.1.2. the Director of the respective Regional Health Inspectorate may revoke the issued order for quarantine upon submission by e-mail of a document showing a negative result from a polymerase chain reaction test conducted within 24 hours of entering the country to prove COVID-19 or by a rapid antigen test as specified in Annex № 2. The recommendation shall be removed within 24 hours upon presentation of the document showing a negative test result.

4.2. Orange zone – allowed on the territory of the country only upon presentation of a valid EU digital COVID certificate for vaccination, for recovery from the illness or for conducted testing, or of a similar document containing the same data as the EU digital COVID certificate.

4.2.1. Not less than 5 percent of the entrants from countries in orange zones are tested for COVID-19 with a rapid antigen test by the border health authorities.

4.2.2. 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 4.2 shall be quarantined for a period of 10 days at home or in another place of accommodation, in which the person has indicated that he/she will reside, with a recommendation issued by the Director of the respective Regional Health Inspectorate or a Deputy Director authorized by him.

4.2.3. The Director of the respective Regional Health Inspectorate may revoke the issued recommendation for quarantine of the persons under item 4.2.2, upon submission by e-mail of a document, showing a negative result from a polymerase chain reaction test conducted within 24 hours of entering the country to prove COVID 19 or from a rapid antigen test as specified in Annex № 2. The recommendation shall be revoked within 24 hours from the presentation of the document showing a negative result from the conducted examination.

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 continuous residence on the territory of the Republic of Bulgaria and their family members;

4.3.2. citizens of the European Union, the European Economic Area and the Swiss Confederation and their family members arriving from a Member State of the European Union, the European Economic Area and the Swiss Confederation;

4.3.3. medical professionals, medical researchers, social workers and their supervisors, where the purpose of the journey is related to the profession they are exercising;

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 and public order services, and humanitarian workers in the performance of their duties, as well as their family members;

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 students, other than those specified in item 5.6., holding a type “D” visa for long-term residence for study purposes;

4.3.10. persons, other than those referred to 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 item 4.3. are allowed on the territory of the country upon presentation of a valid digital EU COVID certificate for vaccination or certificate of recovery or a similar document together with a negative result from a test conducted up to 72 hours before entering the country by the method of polymerase chain reaction for COVID-19, certified by a valid EU digital COVID certificate for testing or a similar document containing the same data as the EU digital COVID certificate for testing.

4.5. The persons under item 4.3.2. - 4.3.10., who do not present a valid EU digital COVID certificate for vaccination or certificate of recovery or a similar document may be admitted on the territory of the country only after presenting a negative result from a test conducted up to 72 hours before entering the country by the method of polymerase chain reaction for COVID-19, certified by a valid EU digital COVID certificate for testing or a similar document containing the same data as the EU digital COVID certificate for testing and they shall be quarantined for a period of 10 days at home or in another place of accommodation, in which the person has indicated that he/she will reside, with a recommendation issued by the Director of the respective Regional Health Inspectorate or a Deputy Director authorized by him.

4.6. Bulgarian citizens and the persons with a status of permanent, long-term or continuous residence on the territory of the Republic of Bulgaria and their family members who do not present any of the documents under item 4.4 shall be quarantined for a period of 10 days at home or in another place of accommodation in which the person has indicated that he/she will reside, with a recommendation issued by the Director of the respective Regional Health Inspectorate or a Deputy Director authorized by him.

4.7. Bulgarian citizens and persons with a status of permanent, long-term or continuous residence on the territory of the Republic of Bulgaria and members of their families, who present upon entering the country only one of the documents specified in item 4.4. (valid EU digital COVID certificate for vaccination or certificate of recovery or a negative result from a polymerase chain reaction test for COVID-19 conducted up to 72 hours before entering the

country, certified by a valid EU digital COVID test certificate or similar document) shall be placed in quarantine for a period of 10 days at home or other place of accommodation in which the person has indicated that he/she will reside, with a recommendation issued by the Director of the respective Regional Health Inspectorate or a Deputy Director authorized by him. In these cases, the Director of the relevant Regional Health Inspectorate may revoke the issued order for quarantine of these persons, upon submission by e-mail of a document showing a negative result from a polymerase chain reaction test conducted within 24 hours of entering the country to prove COVID-19. The recommendation shall be removed within 24 hours upon presentation of the document showing a negative test result.

4.8. Children from the age of 12 to 18 who arrive on the territory of the country from a country falling into the red zone are allowed upon presentation of a negative result from a polymerase chain reaction test for COVID-19 conducted up to 72 hours before entering the country, certified by a valid EU digital COVID test certificate or a similar document containing the same data as the EU digital COVID test certificate. In case they do not present such a document, they shall be placed under quarantine for a period of 10 days at home or other place of accommodation where it is stated that they will reside, with a recommendation issued by the Director of the respective Regional Health Inspectorate or a Deputy Director authorized by him.

4.8.1. The Director of the respective Regional Health Inspectorate may revoke the issued recommendation for quarantine of the children under item 4.8., who are Bulgarian citizens or persons with a status of permanent, long-term or continuous residence on the territory of the Republic of Bulgaria, upon submission by e-mail of a document showing a negative result from a polymerase chain reaction test conducted within 24 hours of entering the country to prove COVID-19. The recommendation shall be removed within 24 hours upon presentation of the document showing a negative test result.

5. On the territory of the country are allowed, without the need to present documents for COVID-19, persons who are:

5.1. bus drivers and stewards engaged in the international carriage of passengers;

5.2. truck drivers who perform or complete international transport of cargo 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 operating 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 North Macedonia, for the purpose of pursuing an activity as an employee or as self-employed person, 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 and students and doctoral students, living in the Hellenic Republic, the Republic of Turkey, the Republic of Serbia, the Republic of North Macedonia and Romania and traveling daily or at least once a week to the Republic of Bulgaria for educational purposes, as well as pupils and students and doctoral students living in the Republic of Bulgaria and traveling daily or at least once a week to the Hellenic Republic, the Republic of Turkey, the Republic of Serbia, the Republic of North 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 their family members, upon arrival from the other country.

6. 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.

7. Persons, with the exception of those under item 5, shall be allowed to the territory of the Republic of Bulgaria only through the following Border Checkpoints (BCs): 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"; Border Checkpoint "Port of Varna"; 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; Kapitan Petko Voivoda Border Checkpoint; Kulata Border Checkpoint; Lesovo Border Checkpoint; Makaza Border Checkpoint; Malko Tarnovo Border Checkpoint; Oltomantsi Border Checkpoint; Oryahovo Border Checkpoint; Ruse Border Checkpoint;

Stanke Lisichkovo Border Checkpoint, Somovit-Nikopol Border Checkpoint and Strezimirovtsi Border Checkpoint.

8. 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.

9. When a passenger with COVID-19 is found on board of an aircraft that has landed on the territory of the Republic of Bulgaria, the cabin crew members who served the passenger with COVID-19 shall not be planned for the next flight and are quarantined for a period of 10 days with a recommendation issued by the Director of the respective Regional Health Inspectorate or by his Deputy Director.

10. For the purposes of this Order:

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

10.2. "Valid EU digital COVID vaccination certificate or a similar document" shall mean 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/she is traveling, 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 regarding vaccines which have two applications, the trade name of the vaccine against COVID-19, the name of the manufacturer/holder of the marketing authorization, the country of issue and the name of the issuing competent authority and, for the EU certificate – including its unique identifier.

10.2.1. A completed vaccination course is considered to be the administration of an appropriate number of doses of a COVID-19 vaccine listed in Annex № 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).

10.3. "Valid EU digital COVID certificate for recovery from the illness" shall mean a document certifying that the person has recovered from COVID-19 and which is valid for the period from the 11th to the 180th day, as of the date of the conducted 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/she travels, date of birth, date of the first positive result of NAAT test (Positive), data of the authority issuing the document, the country in which the test was conducted and its unique identifier. "NAAT test" means a molecular test 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).

10.3.1. A document similar to the EU digital COVID certificate for recovery shall mean 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, as of the date of the conducted 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/she 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 which has conducted the test (name, address or other contact details) or the issuing authority and the country in which the test was conducted.

10.4. “Valid EU COVID certificate for testing” or a similar document shall mean a document showing a negative result from a polymerase chain reaction test conducted up to 72 hours before entry into the country or a negative result from a rapid antigen test conducted up to 48 hours before entry into the country 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/she 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 institution which has conducted the test, country in which the test was conducted and authority that has issued the certificate/document, and for the EU certificate - its unique identifier.

11. Equivalent to the EU digital COVID certificate are also the certificates for COVID-19 issued by a third country, issued by a third country in accordance with standards and technological systems, which are interoperable with the trust framework for the Digital COVID. EU 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 № 4.

II. Order № ПД-01-645 from 28.07.2021, amended by Order № ПД -01-673 from 2.08.2021 and Order № ПД -01-701 from 13.08.2021 is revoked.

III. The Order enters into force as of 01.09.2021.

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, in front of the relevant administrative court under the Administrative Procedure Code.

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DR. STOICHO KATSAROV
Minister of Health

Annex № 1 to item I, 3

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:

The Republic of Austria, the Republic of Poland, the Slovak Republic, Hungary, the Republic of Finland, the Kingdom of Norway, the Vatican City State, the Czech Republic, Luxembourg and Romania.

Orange zone:

All countries outside the green and red zone.

Red zone:

Republic of India, People's Republic of Bangladesh, Federal Democratic Republic of Nepal, Myanmar, Kingdom of Bhutan, Democratic Socialist Republic of Sri Lanka, Republic of Maldives, Republic of South Africa, Republic of Botswana, United Republic of Tanzania, Republic of Seychelles, The Republic of Namibia, The Republic of Zambia, The sultanate of Oman, Malaysia, Turkmenistan, Republic of Tajikistan, Kyrgyz Republic, Mongolia, Republic of Colombia, Republic of Chile, Eastern Republic of Uruguay, Republic of Argentina, Federative Republic of Brazil, Republic of Paraguay, Multinational State of Bolivia, Republic of Peru, Republic of Suriname, Republic of Panama, Republic of Costa Rica, Republic of Guatemala, Belize, the Republic of El Salvador, the Republic of Cuba and the Dominican Republic, the Republic of Cyprus, the United Kingdom of Great Britain and Northern Ireland, Fiji, Georgia, Israel, the Kingdom of Eswatini, the Islamic Republic of Iran, the Republic of North Macedonia, Montenegro, Republic of Kosovo, Republic of Kazakhstan, United States of America, Saint Lucia, Federation of St. Kitts and Nevis and Ireland.

Annex № 2 to items I, 4.1.2

Наименование на теста	Производитель
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 Gold) – Nasal swab	Anhui Deep Blue Medical Technology Co., Ltd
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 Test Kit	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., Ltd
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 HealthCare (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	Biotal Health S.L.U.BIOTAL 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 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
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Genrui Biotech Inc
GenSure COVID-19 Antigen Rapid Test Kit	GenSure Biotech Inc
SARS-CoV-2 Antigen (Colloidal Gold)	Getein Biotech, Inc
One Step Test for SARSCoV-2 Antigen (Colloidal Gold)	Getein Biotech, Inc.
SARS-CoV-2 Antigen Kit (Colloidal Gold)	Goldsite Diagnostic Inc.
GENEDIA W COVID-19 Ag	Green Cross Medical Science Corp.
2019-nCoV Antigen Test Kit (colloidal gold method)	Guangdong Hecin Scientific, Inc.
COVID-2019-nCoV Ag Rapid Test Detection Kit (ImmunoChromatography)	Guangdong Longsee Biomedical Co., Ltd.
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co. Ltd
V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Guangzhou Decheng Biotechnology CO., Ltd
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co., Ltd
COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Hangzhou Lysun Biotechnology Co. Ltd
COVID-19 Antigen Rapid Test	Hangzhou AllTest Biotech Co., Ltd
COVID-19 Antigen Rapid Test Cassette	Hangzhou Clongene Biotech Co., Ltd
Covid-19 Antigen Rapid Test Kit	Hangzhou Clongene Biotech Co., Ltd.
COVID-19/Influenza A+B Antigen Combo Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	Hangzhou Immuno Biotech Co., Ltd
SARS-CoV2 Antigen Rapid Test	Hangzhou Immuno Biotech Co., Ltd
LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co.
Covid-19 Antigen Test Cassette	Hangzhou Testsea Biotechnology Co., Ltd.
Coronavirus Ag Rapid Test Cassette	Healgen Scientific
SARS-CoV-2 Antigen Test Kit	Hubei Jinjian Biology Co., Ltd

Humasis COVID-19 Ag Test	Humasis
Novel Corona Virus (SARSCoV-2) Ag Rapid Test Kit	Jiangsu Bioperfectus Technologies Co., Ltd.
COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	Jiangsu Diagnostics Biotechnology Co., Ltd
SARS-CoV-2 antigen Test Kit (LFIA)	Jiangsu Medomics medical technology Co.,Ltd.
COVID-19 Rapid Antigen Test (Colloidal Gold)	Joinstar Biomedical Technology Co. Ltd
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
SARS-CoV-2 Antigen Rapid Test Kit	Labnovation Technologies Inc.
PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Lumigenex (Suzhou) Co., Ltd
QuickProfile™ COVID-19 Antigen Test	LumiQuick Diagnostics Inc.
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
MEDsan SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
SARS-CoV-2 Antigen Rapid Test Cassette	Merlin Biomedical (Xiamen) Co., Ltd.
MEXACARE COVID-19 Antigen Rapid Test	MEXACARE GmbH
mö-screen Corona Antigen Test	möLab
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals
NADAL COVID -19 Ag +Influenza A/B Test	Nal von minden GmbH
NADAL COVID -19 Ag Test	Nal von minden GmbH
FREND COVID-19 Ag	NanoEntek
NanoRepro SARS-CoV-2 Antigen Rapid Test	NanoRepro AG
MARESKIT COVID-19 ANTIGEN RAPID TEST KIT	NESAPOR EUROPA SL
COVID-19 Antigen Detection Kit	New Gene (Hangzhou) Bioengineering Co., Ltd.
SARS-CoV-2 Antigen Rapid Test	Novatech
CAT	Oncosem Onkolojik Sistemler San. ve Tic. A.S.
PCL COVID19 Ag Rapid FIA	PCL Inc.
PCL COVID19 Ag Gold	PCL Inc.
SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	PerGrande Bio Tech Development Co., Ltd.

Exdia COVID-19 Ag	Precision Biosensor Inc.
Rapid Test Ag 2019-nCov	Prognosis Biotech
SARS-CoV-2 Antigen Rapid Test (Immunochromatography)	Qingdao Hightop Biotech Co. Ltd
Sofia SARS Antigen FIA	Quidel Corporation
LIAISON® Quick Detect Covid Ag Assay	Rapid Pathogen Screening, Inc
SARS-CoV-2 Rapid Antigen Test	Roche (SD BIOSENSOR)
SARS-CoV-2 Rapid Antigen Test Nasal	Roche (SD BIOSENSOR)
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	Shenzhen 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)	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
RapidFor 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 (Immunochromatography)	Wuhan Life Origin Biotech Joint Stock Co., Ltd.
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 Gold)	Zhuhai Lituo Biotechnology Co., Ltd.

Annex № 3 to item I, 10.2.1

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

Annex № 4 to item I, 11

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

Republic of Northern Macedonia, Republic of San Marino, Confederation of Switzerland, Republic of Turkey, Ukraine, Vatican City State (only in respect of vaccination certificates issued).