 **REPUBLIC OF BULGARIA**

 Ministry of Health

 Minister of Health

**ORDER**

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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 connection with Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic and Decision of the Council of Ministers No. 826 of 25 November 2021 extending the term announced by Decision of the Council of Ministers No. 325 of 14 May 2020 epidemic emergency situation, extended by Decision of the Council of Ministers No. 378 of 12 June 2020, Decision of the Council of Ministers No. 418 of 25 June 2020, Decision of the Council of Ministers No. 482 of 15 July 2020, Decision of the Council of Ministers No. 525 of 30 July 2020, Decision of the Council of Ministers No. 609 of 28 August 2020, Decision of the Council of Ministers No. 673 of 25 September 2020, Decision of the Council of Ministers No. 855 of 25 November 2020, Decision of the Council of Ministers No. 72 of 26 January 2021, Decision of the Council of Ministers No. 395 of 28 April 2021, Decision of the Council of Ministers No. 426 of 26 May 2021, Decision of the Council of Ministers No. 547 of 28 July 2021 and Decision of the Council of Ministers No. 629 of 26 August 2021, and a proposal by the Chief State Health Inspector,

**ORDER:**

**I.** I introduce the following temporary anti-epidemic measures regarding the entry of persons arriving from other countries on the territory of the Republic of Bulgaria, as of 01.02.2022 to 31.03.2022, according to an assessment of the spread of COVID-19 in the respective country by criteria and placing countries in colour 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 laboratory tests - relative share in % of positive samples compared to all PCR tests and rapid antigenic tests for SARS-CoV-2 infection in the country in 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 “variant of 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 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 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 per 100,000 population is between 75 and 200 per 100,000 population and the weekly positivity of the laboratory tests conducted is greater than or equal to 4%; or

2.2.2. If at the time of assessment the 14-day incidence 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 per 100,000 population is between 500 and 5,000 per 100,000 population.

**2.4. Dark red zone:**

**2.4.1.** If at the time of assessment the 14-day incidence per 100,000 population is over 5,000 per 100,000 population; or

**2.4.2.** Insufficient information, periodic updates or a reliable source of information on the country concerned, or if the level of the testing is lower than 300 samples per 100,000 population; or

**2.4.3.** If a SARS-CoV-2 variant of concern is spreading in the respective country, taking into account sequencing volumes and transmission levels.

**2.5.** If there is information about a significant negative change in the epidemic situation in the country from green, orange or red zone or in some of its territories, before the official change of the colour zone of the country in relation to persons arriving in the Republic of Bulgaria specific anti-epidemic measures announced in Annex No. 1 may apply.

**3.** The list of countries and overseas territories by colour zones and countries for which a significant negative change in the epidemic situation under item 2.5 has been established is contained in Annex No. 1.

**3.1.** The list under item 3 is determined on the basis of information published by the European Centre 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 Centre of Diseases - Atlanta, USA - for all countries and the spread of variants raising "worry".

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

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

**3.4.** The information under item 3 is monitored and prepared by the National Centre 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 an equivalent or 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 placed under quarantine for 10 days at home or other place of accommodation in which the person has indicated that he / she will reside, with a prescription issued by the Director of the relevant Regional Health Inspectorate or an authorized by him/her a Deputy Director.

**4.1.2.** The quarantined person under item 4.1.1. may perform a polymerase chain reaction test to detect COVID-19 or a rapid antigen test of those listed in Annex No. 2 not earlier than 72 hours of arrival in the country. In case of a negative result of the test performed, the quarantine of the person shall be considered terminated from the day of 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 an equivalent or 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 at home or other place of accommodation in which the person has indicated that he / she will reside, with a prescription issued by the Director of the relevant Regional Health Inspectorate or a Deputy Director authorized by him.

**4.2.2.** The quarantined person under item 4.2.1. may perform a polymerase chain reaction test to detect COVID-19 or a rapid antigen test of those listed in Annex No. 2 not earlier than 72 hours of arrival in the country. In case of a negative result of the test performed, the quarantine of the person shall be considered terminated from the day of registration of the result in the National Information System for Combating COVID-19.

**4.3. Red 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 an equivalent or similar document containing the same data as the EU digital COVID certificate.

**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 members of their families who do not present a document under item 4.3 shall be quarantined for 10 days at home or in another place of accommodation, in which the person has indicated that he / she will reside, with a prescription issued by the Director of the relevant Regional Health Inspectorate or an authorized by him / her a Deputy Director.

**4.3.2.** The quarantined person under item 4.3.1. may perform a polymerase chain reaction test to detect COVID-19 or a rapid antigen test of those listed in Annex No. 2 not earlier than 72 hours of arrival in the country. In case of a negative result of the test performed, the quarantine of the person shall be considered terminated from the day of registration of the result in the National Information System for Combating COVID-19.

**4.4. Dark red zone** - persons are admitted to the territory of the country upon presentation of a valid digital EU COVID certificate for vaccination, recovery or an equivalent or similar document containing the same data as the EU digital COVID certificate, together with a negative result of 72 hours before entry into the country polymerase chain reaction test for COVID-19.

**4.4.1.** Persons under item 4.4 who present a valid EU digital COVID certificate for vaccination for an additional (booster) dose or an equivalent or similar document under item 9.2.2., do not need to present a negative test result from polymerase chain reaction test for COVID-19, performed up to 72 hours before entry into the country

**4.4.2.** 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 any of the documents under item 4.4 are allowed on the territory of the country and placed under quarantine for 10 days at home or elsewhere, in where the person has indicated that he / she will reside, with a prescription issued by the Director of the relevant Regional Health Inspectorate or an authorized by him / her a Deputy Director.

**4.4.3.** 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 present upon entering the country only one of the documents under item 4.4. (for vaccination with a completed vaccination course under item 9.2.1. or for recovery or for a negative result from a test performed up to 72 hours before entry into the country by the method of polymerase chain reaction for COVID-19) are placed under quarantine for a period of 10 days at home or elsewhere, where the person has indicated that he / she will reside, with a prescription issued by the Director of the relevant Regional Health Inspectorate or an authorized by him / her a Deputy Director. The quarantined person may take a polymerase chain reaction test to detect COVID-19 no earlier than 72 hours of arrival in the country. In case of a negative result of the test performed, the quarantine of the person shall be considered terminated from the day of registration of the result in the National Information System for Combating COVID-19.

**4.4.4.** Children under item 4.4. from 12 to 18 years of age are allowed on the territory of the country upon presentation of a valid EU digital COVID certificate for testing or an equivalent or similar document with a negative result from a polymerase chain reaction test for COVID-19, performed up to 72 hours before entering the country. In case they do not present such a document, they shall be quarantined for a period of 10 days at home or in another place of accommodation, where it is stated that they will reside, with a prescription issued by the Director of the relevant Regional Health Inspectorate or an authorized by him / her Deputy Director. The quarantined person may perform a polymerase chain reaction test to detect COVID-19 no earlier than 72 hours of arrival in the country. In case of a negative result of the test performed, the quarantine shall be considered terminated from the day of registration of the result in the National Information System for Combating COVID-19.

**5.** On the territory of the country, without the need to submit documents for COVID-19, regardless of the area from which they arrive, are allowed persons who are:

**5.1.** Drivers and stewards of buses engaged in international passenger transport;

**5.2.** Drivers of trucks that perform or complete the international transport of stocks and goods upon entering the territory of the Republic of Bulgaria;

**5.3.** Members of the crews of vessels and 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 aircrafts that fly to and from airports for public use on the territory of the Republic of Bulgaria and the persons engaged in aircraft maintenance;

**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, in order to work as an employed or 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 self-employed person);

**5.6.** Pupils, students and doctoral students living in the Republic of Greece, the Republic of Turkey, the Republic of Serbia, the Republic of Northern Macedonia and Romania and traveling to the Republic of Bulgaria for education, certified by a document from the relevant institution, as well as students and doctoral students living in the Republic of Bulgaria and traveling to the Republic of Greece, the Republic of Turkey, the Republic of Serbia, the Republic of Northern Macedonia and Romania for the purpose of education, certified by a document from the respective educational institution;

**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.

**6.** Persons, with the exception of those under item 5, are admitted to the territory of the Republic of Bulgaria only through the following border checkpoints (BCP): BCP Burgas Airport; BCP Varna Airport; BCP Plovdiv Airport; BCP Sofia Airport (Terminal 1 and Terminal 2); BCP Port of Bourgas; BCP Port of Varna; BCP Vidin; BCP Vrashka Chuka; BCP Durankulak; BCP Gueshevo; BCP Zlatarevo; BCP Ilinden; BCP Kalotina; BCP Captain Andreevo; BCP Captain Petko Voivoda; BCP Kulata; BCP Lesovo; BCP Makaza; BCP Malko Tarnovo; BCP Oltomantsi; BCP Oryahovo; BCP Ruse; BCP Stanke Lisichkovo; BCP Somovit-Nikopol and BCP Strezimirovtsi.

**7.** 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 stocks and goods destined for other countries, due to a ban by a border state of the Republic of Bulgaria, cannot leave the country.

**8.** Upon identifying 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 a next flight due to being quarantined for term of 7 days with a prescription issued by the Director of the respective regional health inspection or by a Deputy Director authorized by him.

**9.** For the purposes of this order:

**9.1.** "State (territory) from which the person arrives" shall mean the country (territory), which is the starting point of his/her departure, regardless of the stay associated with his/her transit through other countries during his/her travel.

**9.2.** "Valid EU digital COVID vaccination certificate or similar document" shall mean:

**9.2.1.** A document for completed vaccination course against COVID-19, valid from the 15th day to the 270th day from the date of the last dose. 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 last received dose of vaccine against COVID-19, serial number of the dose, and the total number of doses regarding vaccines which have two applications, trade name of the vaccine against COVID-19, name of the manufacturer / holder of the marketing authorization, country of issue and name of the issuing competent authority and, for the EU certificate, its unique identifier. A course of vaccination is considered to be completed when the appropriate number of doses of a vaccine against COVID-19, listed in Annex No. 3 have been applied. Combination of one dose of Vaxzevria / AZD1222 with one dose of Comirnaty/ BNT162b2 vaccine (Pfizer-BioNTech Covid-19 vaccine) is also considered to be a completed vaccination course.

**9.2.2.** A document for an additional (booster) dose of vaccine against COVID-19 after completing a vaccination course. The document must contain the names of the person written in Latin according to the identity document he / she is traveling with, date of birth, date of booster dose of COVID-19 vaccine, serial number of the dose, and total number of vaccine doses, the trade name of the vaccine against COVID-19, the name of the manufacturer / holder of the marketing authorization, the country in which it was issued and the name of the issuing competent authority and, for the EU certificate, its unique identifier.

**9.3.** "Valid EU digital COVID certificate for recovery" shall mean a document certifying that a person has recovered from COVID-19, 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 / she travels, date of birth, date of the first positive result of the NAAT test and a positive result, details of the issuing authority, country, in which the test was performed 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 transcriptional-mediated amplification (TMA) techniques used to detect the presence of ribonucleic acid of SARS-CoV-2 (RNA).

**9.3.1.** Document similar to the EU digital COVID recovery 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, 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, data about the medical institution that performed the test (name, address or other contact details) of the issuing authority and the country where the test was performed.

**9.4.** "Valid EU digital COVID certificate for testing" or 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, as of the date of testing, 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 (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 that performed the test, country where the test was performed and the authority that issued the certificate / document, and for the EU certificate - its unique identifier.

**10.** Equivalent to the EU digital COVID certificate shall also be considered determined as equivalent with an act for implementation of the European Commission COVID-19 certificates, issued by a third country in accordance with standards and technology systems that are interoperable with the EU Digital COVID certificate trust framework. 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 No. 4.

**II.** Order No. RD-01-19 of 14.01.2022, amended by Order No. RD-01-26 of 17.01.2022 is revoked.

**III.** This 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.

**PROF. ASENA SERBEZOVA, PhD**

*Minister of Health*

**Annex No. 1 to p. I, 3**

**List of countries and overseas territories by color zones, countries for which there is information about a significant negative change in the epidemic situation**

**Green zone:**

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**Orange zone:**

All countries outside the green, red and dark red zone.

**Red zone:**

Australia

Austria

Anguilla

Antigua and Barbuda

Barbados

The Bahamas

Belize

Bermuda

Bosnia and Herzegovina

British Virgin Islands

The Grand Duchy of Luxembourg

Grenada

Georgia

Dominica

Dominican Republic

The state of Kuwait

Eastern Republic of Uruguay

Ireland

Italy

Jordan

Cape Verde

Cayman Islands

Canada

Qatar

Kyrgyz Republic

Principality of Liechtenstein

Principality of Monaco

Kingdom of Spain

Kingdom of the Netherlands

Kingdom of Norway

Kingdom of Sweden

Cooperative Republic of Guyana

Kingdom of Bahrain

Curacao

Republic of Lebanon

Multinational Republic of Bolivia

Mongolia

Montserrat

New Caledonia

United Kingdom of Great Britain and Northern Ireland

Isle of Man

Aruba Islands

Republic of Albania

Republic of Argentina

Republic of Botswana

Republic of Greece

Republic of Ecuador

Republic of Estonia

Republic of Kazakhstan

Republic of Colombia

Republic of Kosovo

Republic of Costa Rica

Republic of Latvia

Republic of Lithuania

Republic of Malta

Republic of Moldova

Republic of Panama

Republic of Paraguay

Republic of Peru

Republic of Poland

Republic of Northern Macedonia

Republic of Singapore

Republic of Suriname

Republic of Serbia

Republic of Tajikistan

Republic of Trinidad and Tobago

Republic of Turkey

Republic of Finland

Republic of Chile

Romania

Saint Vincent and the Grenadines

Saint Lucia

Slovak Republic

United States of America

Tunisia

Turkmenistan

Turks and Caicos Islands

Hungary

Federal Republic of Germany

Federal Republic of Brazil

Federation of St. Kids and Navis

Croatia

Montenegro

Czech Republic

Jamaica

**Dark red zone:**

Afghanistan

Boner

Gibraltar

Greenland

Israel

Iceland

Principality of Andorra

Swiss Confederation

Kingdom of Belgium

Kingdom of Denmark

Democratic People's Republic of Korea

Maldives

United Republic of Tanzania

Republic of Palau

The Portuguese Republic

Republic of San Marino

Republic of Seychelles

Saba

Saint Pierre and Miquelon

Sint Eustatius

Slovenia

Faroe Islands

France

**Annex No. 2 to p. I, 4.1.2**

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| **Name of the test** | **Manufacturer** |
| COVID-VIRO® Rapid antigen test COVID-19  | AAZ-LMB  |
| Panbio™ COVID-19 Ag Rapid Test  | Abbott Rapid Diagnostics  |
| Cora Gentest-19 | ABIOTEQ |
| Accu-Tell SARS-CoV-2 Ag Cassette | AccuBioTech Co.,Ltd |
| 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  |
| New Coronavirus (COVID-19) Antigen Rapid Test | Anhui Formaster Biosci 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.  |
| Ksmart® SARS-COV2 Antigen Rapid Test  | Avalun  |
| COVID-19 Antigen Rapid Test  | AXIOM Gesellschaft für Diagnostica und Biochemica mbH  |
| BD Veritor™ System for Rapid Detection of SARS-CoV-2  | Becton Dickinson  |
| BD Kit for Rapid Detection of SARS-CoV-2 | Becton Dickinson |
| Novel Coronavirus 2019nCoV Antigen Test (Colloidal Gold)  | Beijing Hotgen Biotech Co., Ltd  |
| Coronavirus (2019-nCoV)-Antigentest | Beijing Hotgen Biotech Co., Ltd |
| Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit | Beijing Jinwofu Bioengineering Technology Co.,Ltd. |
| COVID19 Antigen Rapid Test Kit | Beijing Kewei Clinical Diagnostic Reagent Inc |
| SARS-CoV-2 Antigen Rapid Test Kit  | Beijing Lepu Medical Technology Co., Ltd  |
| COVID-19 Antigen Rapid Test | Beijing O&D Biotech 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 Antigen Rapid Test (Colloidal Gold Method) | 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  |
| COVID19Speed-Antigen Test BSD\_0503 | BioSpeedia International |
| 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  |
| CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST | Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd.Şti |
| CHECK UP SARS-COV-2 NASOPHARYNGEAL RAPID ANTIGEN TEST | Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd.Şti |
| CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal SwabCasette) | Chil Tıbbi Malzeme Sanayi ve Ticaret Limited Şirketi |
| 2019-nCoV Antigen Test Kit | Chongqing M&D Biotechnology Co. Ltd |
| 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  |
| COVID-19 Antigen Detection Kit | DNA Diagnostic |
| Dräger Antigen Test SARS-CoV-2 | Dräger Safety AG & Co. KGaA |
| Dynamiker SARS-CoV-2 Ag Rapid Test | Dynamiker Biotechnolgy(Tianjin) Co., Ltd. |
| 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 |
| Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) | Genobio Pharmaceutical Co., Ltd. |
| 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.  |
| Novel Coronavirus (2019- nCoV) Antigen Test Kit (Colloidal gold immunochromatography) | Glallergen CO., LTD |
| 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 TestDetection Kit (ImmunoChromatography) | Guangdong Longsee Biomedical Co., Ltd.  |
| COVID-19 Ag Test Kit  | Guangdong Wesail Biotech 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(Nasal Swab) | Hangzhou Biotest Biotech Co., Ltd |
| COVID-19 Antigen Rapid Test Casette  | 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  |
| Redtest Professional SarsCoV-2 Antigen Rapid Test (Covid-19 Ag) | Sigmed Sp. z o.o. |
| COVID-19 Antigen Test Cassette | Hangzhou DIAN Biotechnology Co., Ltd. |
| LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)  | Hangzhou Laihe Biotech Co.  |
| COVID-19 Antigen Rapid Test Device (Colloidal Gold) | Hangzhou Lysun Biotechnology Co. Ltd |
| SARS-CoV-2 Antigen Rapid Test Cassette | Hangzhou Sejoy Electronics & Instruments Co.Ltd |
| Covid-19 Antigen Test Cassette  | Hangzhou Testsea Biotechnology Co., Ltd.  |
| Coronavirus Ag Rapid Test Cassette  | Healgen Scientific  |
| CLINITEST Rapid COVID-19 Antigen Test | Siemens Healthineers |
| Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold) | Hoyotek Biomedical Co.,Ltd. |
| SARS-CoV-2 Antigen Test Kit | Hubei Jinjian Biology Co., Ltd |
| Humasis COVID-19 Ag Test  | Humasis  |
| Innova SARS-CoV-2 Antigen Rapid Qualitative Test | Innova Medical Group.Inc |
| Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Nasal swab) | Innovation Biotech(Beijing) Co.Ltd |
| Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen) | InTec PRODUCTS, INC. |
| 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.  |
| SARS-CoV-2 Antigen Test Cassette | Jiangsu Mole Bioscience CO., LTD. |
| COVID-19 Ag Rapid Test Device | Jiangsu Well Biotech Co., Ltd. |
| COVID-19 Rapid Antigen Test (Colloidal Gold)  | Joinstar Biomedical Technology Co. Ltd  |
| Covid-19 Antigen Schnelltest (Colloidales Gold) | IEDAU INTERNATIONAL GMBH |
| 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.  |
| COVID-19 Antigen Test Kit (Colloidal Gold) | LINKCARE (NANTONG DIAGNOS BIO) |
| 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  |
| COVIOS Ag COVID-19 Antigen Rapid Diagnostic Test | Mologic Ltd |
| 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  |
| StrongStep® SARS-CoV-2 Antigen Rapid Test | Nanjing Liming Bio-Products Co., Ltd. |
| Novel Coronavirus (2019- nCoV) Antigen Testing Kit (Colloidal Gold) | Nanjing Norman Biological Technology Co., Ltd. |
| SARS-COV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method) | Nanjing Synthgene Medical Technology Co., Ltd. |
| 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.  |
| Ninonasal | NG Biotech |
| SARS-CoV-2 Antigen Rapid Test  | Novatech  |
| CAT  | Oncosem Onkolojik Sistemler San. ve Tic. A.S.  |
| GeneFinder COVID-19 Ag Plus Rapid Test | OSANG Healthcare Co., Ltd. |
| 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 COVI-19 Ag  | Precision Biosensor Inc.  |
| Rapid Test Ag 2019-nCov  | Prognosis Biotech  |
| SARS-CoV-2 Antigen Rapid Test (Immunochromatography)  | Qingdao Hightop Biotech Co. Ltd  |
| SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test | 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  |
| SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method) | Sansure Biotech Inc |
| ScheBo SARS CoV-2 Quick Antigen  | ScheBo Biotech  |
| ScheBo SARS CoV-2 Quick ANTIGEN (Colloidal Gold Method) | ScheBo Biotech |
| 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  |
| SARS-CoV-2-Antigen Rapid Detection Kit | Shenzhen CAS Envision Medical Technology Co., Ltd |
| SARS-CoV-2 Antigen Test Kit (Colloidal Gold) | Shenzhen Dymind Biotechnology Co., Ltd |
| SARS-CoV-2 Antigen Test Kit (Colloidal Gold) | Shenzhen Huian Biosci Technology Co., Ltd |
| SARS-CoV-2 Antigen Test Kit (GICA) | Shenzhen Kisshealth Biotechnology 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 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay) | Shenzhen Microprofit Biotech Co., Ltd |
| SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay) | Shenzhen Microprofit Biotech Co., Ltd |
| SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence) | Shenzhen Reagent Technology 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  |
| GLINE-2019-nCoV Ag | Shenzhen YHLO Biotech Co., Ltd. |
| Zhenrui ®COVID-19 Antigen Test Cassette  | Shenzhen Zhenrui Biotech Co., Ltd  |
| SGTi-flex COVID-19 Ag  | Sugentech, Inc.  |
| SARS-CoV-2 Rapid Antigen Test Cassette | SureScreen Diagnostics |
| COVID-19 Antigen Test Kit | Surge Medical 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  |
| INFO Covid-19 Ag Test | TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş. |
| Covid-19 Ag Test | TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş. |
| RAPIDAN TESTER Covid-19 Ag Test | TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş. |
| TOYO Covid-19 Ag Tes | TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş. |
| Rapid For SARS-CoV-2 Rapid Ag Test  | Vitrosens Biotechnology Co., Ltd  |
| Verino 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.  |
| SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay) | Wuxi Biohermes Bio & Medical Technology 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  |
| Pantest Coronavirus Ag (Nasopharyngeal Swab) | Pantest SA |
| Novel Coronavirus (COVID-19) Antigen Detection Kit (Swab) | Zhejiang GENE SCIENCE Co., Ltd |
| Coronavirus Ag Rapid Test Cassette (Swab)  | Zhejiang Orient Gene Biotech Co., Ltd  |
| ENCODE SARS-COV-2 Antigen Rapid Test Device | Zhuhai Encode Medical Engineering Co.,Ltd |
| COVID-19 Antigen Detection Kit (Colloidal Gold)  | Zhuhai Lituo Biotechnology Co., Ltd.  |

**Annex No. 3 to p. I, 9.2.1.**

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| --- | --- | --- |
| **Trade name of the vaccine according to the EU marketing authorization / WHO list** | **Name of the manufacturer / holder of the marketing authorization** | **Completed vaccination course** |
| Comirnaty/ (/ BNT162b2 Pfizer-BioNTech Covid-19 vaccine) | BioNTech Manufacturing GmbH/ Pfizer-Biontech | 2 dozes |
| Vaxzevria/ AZD1222 |  AstraZeneca WCH/ AstraZeneca Canada Inc. | 2 dozes |
| - / AZD1222 | SK Bioscience Co Ltd | 2 dozes |
| Spikevax/COVID-19 VACCINE Moderna / mRNA-1273 | MODERNA BIOTECH | 2 dozes |
| Janssen / Ad26.COV2.S | Janssen-Cilag International NV | 1 doze |
| - / Covishield (ChAdOx1\_nCoV-19) | Serum Institute of India | 2 dozes |
| - / SARS-CoV-2 Vaccine (Vero Cell), Inactivated (lnCoV) | Sinopharm / BIBP1 | 2 dozes |
| - / COVID-19 Vaccine (Vero Cell), Inactivated/Coronavac | Sinovac | 2 dozes |
| - / Sputnik V(Gam-COVID-VacComponent I Gam-COVID-Vac Component II) | The Gamaleya National Centre of Epidemiology and Microbiology | 2 dozes |
| SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN | Bharat Biotech, India | 2 dozes |

**Annex No. 4 to p. I, 10**

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

Armenia, Georgia, Vatican City State (only for vaccination certificates), Israel, Eastern Republic of Uruguay, Iceland, Cape Verde, Principality of Andorra, Principality of Liechtenstein, Principality of Monaco, Confederation of Switzerland, Kingdom of Morocco, Kingdom of Norway, Kingdom of Thailand, Lebanese Republic, New Zealand, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, Republic of Albania, Republic of El Salvador, Republic of Moldova, Republic of Panama, Republic of San Marino, Republic of Northern Macedonia, Republic of Singapore, Republic of Serbia, Republic of Turkey, Taiwan, Togolese Republic, Tunisia, Ukraine, Faroe Islands and Montenegro.