



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 dated 14 June 2021 on a framework for the issuance, verification and adoption of interoperable vaccination certificates against COVID -19 (EU COVID Digital Certificate) to facilitate free movement during the COVID-19 pandemic, Commission Delegated Regulation (EU) 2021/2288 dated 21 December 2021 amending the Annex to Regulation (EU) 2021 / 953 of the European Parliament and of the Council as regards the period of acceptance of vaccination certificates issued in the EU's Digital COVID format, indicating that the main vaccination series has been completed, Commission Delegated Regulation (EU) 2022/256 dated 22 February 2022 amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issue of certificates for getting through the disease on the basis of a rapid test for antigens, Decision № 826 of the Council of Ministers dated 25 November 2021 extending the emergency epidemic situation declared by Decision № 325 of the Council of Ministers dated 14 May 2020, extended by Decision № 378 of the Council of Ministers dated 12 June 2020 Decision № 418 of 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 28 June 2020 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 proposal of the Chief State health inspector

### I 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, from 10.03.2022 to 31.03.2022, according to the assessment of the spread of COVID-19 in the respective country by criteria and placing countries in color zones, as follows:

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

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

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

1.3. level of research 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 "worry" variant;

1.5. lack of sufficient information, periodic updating of information or a reliable source of information about certain 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 performed 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 performed 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 over 500 per 100,000 population.

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

2.3.3. if a SARS-CoV-2 variant is of concern in the country concerned, taking into account sequencing volumes and transmission levels.

2.4. 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 color zone of the country in relation to persons arriving in the Republic of Bulgaria may apply specific anti-epidemic measures announced in Annex № 1.

3. The list of countries and territories by color zones and countries for which a significant negative change in the epidemic situation under item 2.4 has been established is defined 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), the World Health Organization and the Control Center of Diseases - Atlanta, USA - for all countries and the spread of "worry" options.

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

3.3. The list under item 3 shall be reviewed periodically and, if necessary, updated every 14 days, and in the event 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 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, getting through the disease 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 in the home or other place of accommodation in which the person has indicated that s/he will reside, with a prescription issued by the director of the relevant regional health inspectorate or authorized by his 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 of those listed in Annex № 2 not earlier than 72 hours of arrival in the country. In case of a negative result of the conducted research, 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, getting through the disease 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 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 of those listed in Annex № 2 not earlier than 72 hours of arrival in the country. In case of a negative result of the conducted research, 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, getting through the disease 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 extended 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 elsewhere, in which the person has indicated that s/he will reside, with a prescription issued by the director of the respective regional health inspectorate or a deputy director authorized by him.

4.3.2. The quarantined person under item 4.3.1. may carry out a polymerase chain reaction test to detect COVID-19 or a rapid antigen test of those listed in Annex № 2 not earlier than 72 hours of arrival in the country. In case of a negative result of the conducted research, 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. Persons arriving from Ukraine, regardless of the zone in which the country currently falls at the time of arrival, are admitted to the country upon presentation of a valid EU digital COVID certificate for vaccination, getting through the disease or testing, or an equivalent or similar document containing the same data as the EU digital COVID certificate. Persons who do not present such a document shall be quarantined for a period of 10 days in the home or other place of accommodation in which the person has indicated that s/he will reside, with a prescription issued by the director of the relevant regional health inspectorate or authorized by him deputy director.

4.5. The quarantined person under item 4.4. may carry out a polymerase chain reaction test to detect COVID-19 or a rapid antigen test of those listed in Annex № 2 not earlier than 72 hours of arrival in the country. In case of a negative result of the conducted research, 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.

5. On the territory of the country are allowed, without the need to submit documents for COVID-19, regardless of the zone from which persons have arrived, 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 goods 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 flies 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 Hellenic Republic, the Republic of Turkey, the Republic of Serbia, the Republic of Northern Macedonia and Romania and traveling to the Republic of Bulgaria for training certified by a document from the relevant institution, as well as students and doctoral students in the Republic of Bulgaria and travel to the Republic of Greece, the Republic of Turkey, the

Republic of Serbia, the Republic of Northern Macedonia and Romania for the purpose of training, 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, shall be admitted to 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; Kardam border checkpoint; Kulata border checkpoint; Lesovo border checkpoint; Makaza border checkpoint; Malko Tarnovo border checkpoint; Oltomantsi border checkpoint; Oryahovo border checkpoint; Ruse border checkpoint; Silistra border checkpoint; Somovit-Nikopol border checkpoint; Stanke Lisichkovo border checkpoint and Strezimirovtsi border checkpoint.

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

8. When 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 the next flight by 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" means the country (territory) - the starting point of his/hers departure, regardless of the stay associated with his transit through other countries during his movement.

9.2. "Valid EU digital COVID vaccination certificate or similar document" means:

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 travels, date of birth, date on which the last received dose of vaccine against COVID-19 was given, serial number of the dose, and the total number of doses in double vaccines, 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. The completion of a vaccination course is considered to be the appropriate number of doses of a COVID-19 vaccine listed in Annex № 3. The combination of one dose of Vaxzevria / AZD1222 with one dose of Comirnaty / BNT162b2 (Pfizer-BioNTech Covid-19 vaccine) is also considered 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 the 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 getting through the disease" is a document certifying that a person has got through COVID-19 and which is valid for the period from the 11th to the 180th day from the date of the study entered in the document. The certificate must contain the names of the person written in Latin according to the identity document with which s/he is traveling, date of birth, date of the first positive result of the NAAT test or date of the first positive result of a rapid antigen test included in the Committee's for health security approval, a common EU list of COVID-19 antigen tests performed by medical professionals or qualified testing staff and a positive result (Positive), details of the issuing authority, country in which the study 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. A document analogous to the EU's digital COVID certificate of getting through the disease is a document certifying that a person has got through COVID-19, and which is valid for the period from the 11th to the 180th day from the date of the study entered in the document. The document must contain the names of the person, according to the identity document with which s/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 that performed the study (name, address or other contact details) or the issuing authority and the country where the study was performed.

9.4. "Valid EU digital COVID 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 fast antigen test conducted up to 48 hours before entry into the country, as of 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 s/he travels, date of birth, type of test, written in Latin method (PCR or RAT) and negative result (Negative), date and time of collection 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 authority that issued the certificate / document, and for the EU certificate - and its unique identifier.

10. Equivalent to the EU digital COVID certificate are also COVID-19 certificates issued by a third country in accordance with standards and technological systems that are interoperable with the Digital EU certificate COVID Trust Framework. The list of countries (territories) whose COVID-19 vaccination, testing and disease certificates are considered equivalent to the EU digital COVID is set out in Annex № 4.

II. Order № RD-01-49 dated 28.01.2022, amended by Order № RD-01-68 dated 03.02.2022, Order № RD-01-85 dated 15.02.2022, Order № RD-01- 109 dated 25.02.2022 and Order № RD-01-114 dated 1.03.2022 is revoked.

III. 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.

PROF. ASENSA SERBEZOVA, PhD

Minister of Health

Annex № 1 to item I, 3

List of countries and territories by color zones, and of 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 and red zone.

Red zone:

Australia  
Austria  
Andorra  
Afghanistan  
Barbados  
Bahrain  
Belgium  
Bermuda  
Brunei  
Bhutan  
Great Britain  
Vietnam  
Germany  
Gibraltar  
Georgia  
Greece  
Denmark  
Dominica  
Estonia  
Israel  
Ireland  
Iceland

Spain  
Italy  
Jordan  
Cayman Islands  
Cyprus  
Democratic People's Republic of Korea  
Costa Rica  
Latvia  
Lithuania  
Liechtenstein  
Luxembourg  
Mauritius  
Maldives  
Monaco  
The Netherlands  
New Zealand  
New Caledonia  
Norway  
Isle of Man  
Palau  
Portugal  
Republic of Korea  
Romania

Russia  
 San Marino  
 Saint Pierre and Miquelon  
 Singapore  
 Slovakia  
 Slovenia  
 Serbia  
 Tanzania  
 Tonga  
 Turkey

Ukraine  
 Uruguay  
 Faroe Islands  
 Finland  
 France  
 French Polynesia  
 Croatia  
 Czech Republic  
 Chile  
 Switzerland  
 Japan

**Annex № 2 to item I, 4.1.2**

<b>Name of the test</b>	<b>Manufacturer</b>
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 HealthCcare (Hefei) Co., Ltd.
SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)	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
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 (Colloidal 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 № 3 to item I, 9.2.1.**

<b>Trade name of the vaccine according to the EU marketing authorization / WHO list</b>	<b>Name of the manufacturer / holder of the marketing authorization</b>	<b>Completed vaccination course</b>
Comirnaty/ (/ BNT162b2 Pfizer-BioNTech Covid-19 vaccine)	BioNTech Manufacturing GmbH/ Pfizer-Biontech	2 doses
Vaxzevria/ AZD1222	AstraZeneca AB	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 Pvt. Ltd	2 doses
- / SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	Sinopharm / BIBP1	2 doses
- / COVID-19 Vaccine (Vero Cell), Inactivated/Coronavac	Sinovac Life Sciences Co., Ltd.	2 doses
- / Sputnik V	Russian Direct Investment Fund	2 doses
Nuvaxovid /NVX-CoV2373	Novavax	2 doses
- /NVX-CoV2373/Covovax	Serum Institute of India Pvt. Ltd	2 doses