

Guidelines on

# Value Sets for EU Digital COVID Certificates

Version 1.7

2022-01-12

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth.

These guidelines complement and further specify the description of value sets as provided by Annex II of the Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council.

Adopted by the eHealth Network on 12 January 2022.

# **Version history**

Version	Date	Changes
1.0	21 April 2021	First adopted version
1.1	12 May 2021	JSON schema detached
1.2	7 July 2021	Update name of the document, names of data fields and reference to the JSON schema specification, add new values
1.3	29 September 2021	Summary table of vaccine coding, addition of new values
1.4	13 October 2021	Addition of new values, technical clarifications
1.5	10 November 2021	Addition of new values, addition of a disclaimer regarding the vaccines
1.6	1 December 2021	Addition of new values, Removel of information fully described in the Implementing Decision
1.7	12 January 2022	Addition of new values

## **Table of Contents**

1	Introduction	5
2	Value Sets for the Digital COVID Certificates	5
	2.1 Disease or agent targeted / Disease or agent the citizen has recovered from	5
	2.2 COVID-19 vaccine or prophylaxis	5
	2.3 Vaccine medicinal product	6
	2.4 COVID-19 vaccine marketing authorization holder or manufacturer	8
	2.5 Number in a series of doses as well as the overall number of doses in the series	<b>3 10</b>
	2.6 Member State or third country in which the vaccine was administered/test was carried out	
	2.7 Type of test	. 10
	2.8 Manufacturer and commercial name of the test used (optional for NAAT test) .	. 10
	2.9 Result of the test	. 10
Anı	nex A Summary of vaccine coding instructions	. 11

#### 1 Introduction

Value Sets for the EU Digital COVID Certificate are defined for the datasets provided in the 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 (Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.

Annex II of the <u>Commission Implementing Decision (EU) 2021/1073</u> of 28 June 2021, amended by <u>Commission Implementing Decision (EU) 2021/2014</u> of 17 November 2021 describes general rules for all value sets and lists some of them in their entirety.

However, for value sets that are changing often, notably related to vaccine and test device coding, the Implementing Decision indicates that they shall be published and regularly updated by the Commission with the support of the eHealth Network and the Health Security Committee. These guidelines provide this publication.

#### **2** Value Sets for the Digital COVID Certificates

#### 2.1 Disease or agent targeted / Disease or agent the citizen has recovered from

Fully described in the Implementing Decision.

#### 2.2 COVID-19 vaccine or prophylaxis

The following codes shall be used.

Code	Display	Code System name	Code System URL	Code System OID	Code System version
1119305005	SARS-CoV-2 antigen vaccine	SNOMED CT	http://snomed.info/sct	2.16.840.1.113883.6.96	2021-01- 31
1119349007	SARS-CoV-2 mRNA vaccine	SNOMED CT	http://snomed.info/sct	2.16.840.1.113883.6.96	2021-01- 31
J07BX03	covid-19 vaccines	Anatomical Therapeutic Chemical Classification System	http://www.whocc.no/atc	2.16.840.1.113883.6.73	2021-01

The code from the ATC can be used for vaccines that are neither an antigen nor an mRNA vaccine or in cases where this information is not known.

#### 2.3 Vaccine medicinal product<sup>1</sup>

(More info on COVID-19 vaccines here).

The following codes shall be used:

Code	Display	Code System name	Code System URL	Code System OID	Code System version
EU/1/20/1528	Comirnaty	Union Register of medicinal products	https://ec.europa.eu/heal th/documents/communit y-register/html/	-	
EU/1/20/1507	Spikevax	Union Register of medicinal products	https://ec.europa.eu/heal th/documents/communit y-register/html/	-	
EU/1/21/1529	Vaxzevria	Union Register of medicinal products	https://ec.europa.eu/heal th/documents/communit y-register/html/	-	
EU/1/20/1525	COVID-19 Vaccine Janssen	Union Register of medicinal products	https://ec.europa.eu/heal th/documents/communit y-register/html/	-	
CVnCoV	CVnCoV	Vaccine medicinal products not centrally authorized in the EU in rolling review by EMA		-	1.0
NVX-CoV2373 (deprecated, see Annex A for more instructions)	NVX- CoV2373	Vaccine medicinal products not centrally authorized in the EU in rolling review by EMA		-	1.0
Sputnik-V	Sputnik V	Vaccine medicinal products not centrally authorized in the EU in rolling review by EMA		-	1.0
Convidecia	Convidecia	Vaccine medicinal products not centrally authorized in the EU		-	1.0
<i>EpiVacCorona</i>	EpiVacCoron a	Vaccine medicinal products not centrally authorized in the EU		-	1.0
BBIBP-CorV	BBIBP-CorV	Vaccine medicinal products not centrally authorized in the EU		-	1.0

<sup>&</sup>lt;sup>1</sup> The fact that a COVID-19 vaccine is listed does not mean that a certificate issued for the administration of such a COVID-19 vaccine will be accepted by EU Member States. The acceptance of vaccination certificates is governed by Article 5(5) of Regulation (EU) 2021/953. Some vaccines on the list may have not been evaluated by EMA or completed the enlistment on the WHO Emergency Use Listing.

Code	Display	Code System name	Code System URL	Code System OID	Code System version
Inactivated- SARS-CoV-2- Vero-Cell (deprecated, see Annex A for more instructions)	Inactivated SARS-CoV-2 (Vero Cell)	Vaccine medicinal products not centrally authorized in the EU		-	1.0
CoronaVac	CoronaVac	Vaccine medicinal products not centrally authorized in the EU		-	1.0
Covaxin	Covaxin (also known as BBV152 A, B, C)	Vaccine medicinal products not centrally authorized in the EU		-	1.0
Covishield	Covishield (ChAdOx1_n CoV-19)	Vaccine medicinal products not centrally authorized in the EU		-	1.2
Covid-19- recombinant	Covid-19 (recombinant	Vaccine medicinal products not centrally authorized in the EU		-	1.3
R-COVI	R-COVI	Vaccine medicinal products not centrally authorized in the EU		-	1.3
CoviVac	CoviVac	Vaccine medicinal products not centrally authorized in the EU		-	1.4
Sputnik-Light	Sputnik Light	Vaccine medicinal products not centrally authorized in the EU		-	1.4
Hayat-Vax	Hayat-Vax	Vaccine medicinal products not centrally authorized in the EU		-	1.4
Abdala	Abdala	Vaccine medicinal products not centrally authorized in the EU		-	1.5
WIBP-CorV	WIBP-CorV	Vaccine medicinal products not centrally authorized in the EU		-	1.5
MVC- COV1901	MVC COVID-19 vaccine	Vaccine medicinal products not centrally authorized in the EU		-	1.6

Code	Display	Code System name	Code System URL	Code System OID	Code System version
EU/1/21/1618	Nuvaxovid	Union Register of medicinal products	https://ec.europa.eu/heal th/documents/communit y-register/html/	-	

#### 2.4 COVID-19 vaccine marketing authorization holder or manufacturer

The following codes shall be used:

Code	Display	Code System name	Code System URL	Code System OID	Code System version
ORG- 100001699	AstraZeneca AB	EMA SPOR- Organisations Management System	https://spor.ema.europa.eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100030215	Biontech Manufacturing GmbH	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100001417	Janssen-Cilag International	EMA SPOR- Organisations Management System	https://spor.ema.europa.eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100031184	Moderna Biotech Spain S.L.	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100006270	Curevac AG	EMA SPOR- Organisations Management System	https://spor.ema.europa.eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100013793	CanSino Biologics	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100020693	China Sinopharm International Corp Beijing location	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100010771	Sinopharm Weiqida Europe Pharmaceutical	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	

Code	Display	Code System name	Code System URL	Code System OID	Code System version
	s.r.o Prague location				
ORG- 100024420	Sinopharm Zhijun (Shenzhen) Pharmaceutical Co. Ltd Shenzhen location	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
ORG- 100032020	Novavax CZ a.s.	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
Gamaleya- Research- Institute	Gamaleya Research Institute	Vaccine Manufacturers not in OMS		-	1.0
Vector- Institute	Vector Institute	Vaccine Manufacturers not in OMS		-	1.0
Sinovac- Biotech	Sinovac Biotech	Vaccine Manufacturers not in OMS		-	1.0
Bharat- Biotech	Bharat Biotech	Vaccine Manufacturers not in OMS		-	1.0
ORG- 100001981	Serum Institute Of India Private Limited	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
Fiocruz	Fiocruz	Vaccine Manufacturers not in OMS		-	1.3
ORG- 100007893	R-Pharm CJSC	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
Chumakov- Federal- Scientific- Center	Chumakov Federal Scientific Center for Research and Development of Immune-and- Biological Products	Vaccine Manufacturers not in OMS		-	1.4

Code	Display	Code System name	Code System URL	Code System OID	Code System version
ORG- 100023050	Gulf Pharmaceutical Industries	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	
CIGB	Center for Genetic Engineering and Biotechnology (CIGB)	Vaccine Manufacturers not in OMS		-	1.5
Sinopharm- WIBP	Sinopharm - Wuhan Institute of Biological Products	Vaccine Manufacturers not in OMS		-	1.5
ORG- 100033914	Medigen Vaccine Biologics Corporation	EMA SPOR- Organisations Management System	https://spor.ema.europa. eu/v1/organisations	2.16.840.1.1138 83.3.6905.4	

#### 2.5 Number in a series of doses as well as the overall number of doses in the series

Fully described in the Implementing Decision.

# 2.6 Member State or third country in which the vaccine was administered/test was carried out

Described in the Implementing Decision.

Additional codes:

XK	Kosovo, Republic of
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#### 2.7 Type of test

Fully described in the Implementing Decision.

#### 2.8 Manufacturer and commercial name of the test used (optional for NAAT test)

Fully described in the Implementing Decision.

#### 2.9 Result of the test

Fully described in the Implementing Decision.

#### Annex A Summary of vaccine coding instructions

The table below shows the coding combinations of the different vaccine medicinal products with their recommended ATC or SNOMED CT 'Vaccine' concept, along with their corresponding marketing authorization holder or manufacturer. The table is included to assist implementation efforts.

As presented in the Value Sets above, for some vaccine medicinal products and marketing authorization holders or manufacturers, the applicable code is based on their names, using a hyphen to avoid blank spaces. Also, note, the comment included earlier for the Vaccine marketing authorization holder or manufacturer Value Set about the use of the OMS identifier of EU marketing authorization holder, as there is no internationally agreed coding.

Vaccine name	Vaccine code	Vaccine Manufacturer or MAH code	Vaccine type	Note
Comirnaty	EU/1/20/1528	ORG-100030215	1119349007 or J07BX03	
Spikevax	EU/1/20/1507	ORG-100031184	1119349007 or J07BX03	Previously COVID-19 Vaccine Moderna.
Vaxzevria	EU/1/21/1529	ORG-100001699	J07BX03	Use also for AstraZeneca covid-19 vaccines, except R-COVI, Covishield and Covid-19 (recombinant) by Fiocruz.
COVID-19 Vaccine Janssen	EU/1/20/1525	ORG-100001417	J07BX03	
CVnCoV	CVnCoV	ORG-100006270	1119349007 or J07BX03	

Vaccine name	Vaccine code	Vaccine Manufacturer or MAH code	Vaccine type	Note
NVX-CoV2373	NVX-CoV2373	ORG-100032020	J07BX03	Do not use this code for new certificates, see entry for Nuvaxovid.
Sputnik V	Sputnik-V	Gamaleya-Research-Institute	J07BX03	
Convidecia	Convidecia	ORG-100013793	J07BX03	
EpiVacCorona	EpiVacCorona	Vector-Institute	J07BX03	
BBIBP-CorV	BBIBP-CorV	ORG-100020693	J07BX03	
Inactivated SARS-CoV-2 (Vero Cell)	Inactivated-SARS-CoV-2-Vero-Cell	ORG-100010771	J07BX03	Do not use this code for new certificates, see entry for WIBP-CorV.
CoronaVac	CoronaVac	Sinovac-Biotech	J07BX03	
Covaxin (also known as BBV152 A, B, C)	Covaxin	Bharat-Biotech	J07BX03	
Covishield (ChAdOx1_nCoV-19)	Covishield	ORG-100001981	J07BX03	
Covid-19 (recombinant)	Covid-19- recombinant	Fiocruz	J07BX03	
R-COVI	R-COVI	ORG-100007893	J07BX03	
CoviVac	CoviVac	Chumakov-Federal-Scientific- Center	J07BX03	
Sputnik Light	Sputnik-Light	Gamaleya-Research-Institute	J07BX03	
Hayat-Vax	Hayat-Vax	ORG-100023050	J07BX03	
Abdala	Abdala	CIGB	J07BX03	Also known as CIGB-66.

Vaccine name	Vaccine code	Vaccine Manufacturer or MAH code	Vaccine type	Note
WIBP-CorV	WIBP-CorV	Sinopharm-WIBP	J07BX03	Previously known as Inactivated SARS-CoV-2 (Vero Cell).
MVC COVID-19 vaccine	MVC-COV1901	ORG-100033914	J07BX03	Also known as Medigen COVID-19 vaccine.
Nuvaxovid	EU/1/21/1618	ORG-100032020	J07BX03	Previously known as NVX-CoV2373.