



Functional and Non-Functional Requirements Update Document

Component 1 LACPASS

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DE COOPERACION
SOBRE SALUD
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Introduction	2
Updates to the current regulation for the exchange of certificates	3
Basic Concepts for the Certificates	4
Requirements	4
COVID-19 Vaccination Certificate	6
Requirements	6
COVID-19 Testing Certificate	7
Requirements	7
COVID-19 Recovery Certificate	9
Requirements	9
Updates to Non-Functional Requirements	10
Glossary	11
Bibliography	13

Introduction

At present, the European Union has implemented an interoperability for the COVID-19 certificates between member countries, as well as some non-member countries who meet the requirements defined by the EU.

However, and because the health situation is constantly evolving with the appearance of new variants, the requirements and the data related to the certificates is also evolving together with the health situation.

Because of this, the EU is constantly analyzing the health situation to keep traffic flowing. That is why they always review the requirements and the data that must always be included in the different COVID-19 certificates, which allow them to continue with their interoperability and to ensure the free movement of people.

This document expands on the information included in the [Functional and Non-Functional Requirements for a Proof of Concept](#) and the [Minimum Amount of Data](#) documents. It will also provide a description of the last modifications that were introduced by the EU.

Updates to the current regulation for the exchange of certificates

Because the pandemic is still at large, and because new strains of the virus have arisen that can cause public health issues, Digital Certificates can still contribute and monitor the health situation of all countries using them as a way to control borders. They also help prevent the continuous spread of the new strains.

Therefore, and as long as the World Health Organization's declaration of a pandemic situation remains in effect, these certificates will still need to be used for cross-border travel.

Following is a description of the modifications introduced by the EU regarding the requirements or the data for the Digital Certificates currently being used by the community for cross-border travel.

In their document¹, the WHO updated the functional and non-functional requirements for COVID-19 certificates; therefore, this document will only describe the modified requirements or any new requirements that have been introduced in the document.

As for the minimum amount of data, this document will only mention that they will use the HL7 FHIR format included in the following web pages:

- <https://www.hl7.org/fhir/datatypes.html#dateTime%20>
- <https://worldhealthorganization.github.io/ddcc/>

¹ WHO – Digital Documentation of COVID-19 Certificates: Testing Results. Technical Specifications and Implementation Guidance. March 31st, 2022.

Basic Concepts for the Certificates

One of the major modifications that impact the three types of certificates concerns their usage time. This time has now been extended to 12 more months within the EU, extending their use until July 2023.

Requirements

The following is a detailed description of the modifications to the functional requirements applicable to all three certificates².

Requirement	Description	Modification
General	Universal, timely and affordable access to vaccines, to COVID-19 tests, are the bases to issue them.	There can be no discriminations in the issuing of certificates based on the nationality of the individual interested in accessing the certificate.
General	All certificates must be issued automatically or upon previous request.	All countries are required to issue the three certificates in keeping with the recommendations standards that allow for the certificates to be accepted.
General	A certificate can be issued to another person on behalf of the vaccinated individual, tested or recovered. For example, to the legal guardian of a legally incapacitated individual, or to parents on behalf of their children. Certificates must not be subject to legislation or any other similar formalities.	Any individual who does not submit a valid certificate can be requested to undergo a test, presenting the results within 24 hours of their arrival.
General	All countries involved must have a clear, complete, and timely communication with the public regarding the fidelity, issuance, and acceptance of each of the certificate types.	<p>The restrictions must be lifted when the health epidemic situation of the countries allows it.</p> <p>In so doing, the certificates should not be applied anymore once the pandemic is over.</p> <p>All member countries have an obligation to inform of any restriction modifications at least 48 hours before they go into effect.</p>
General	A date must be set for a gradual introduction so that countries that cannot issue certificates in	Currently, if a country decides NOT to request COVID certificates for a person to enter the country anymore,

² Functional and Non-Functional Requirements for a Proof of Concept, page 7.

	<p>the defined format can still issue certificates that do not yet comply with the standards established. During this period, the rest of the countries must accept the issued certificates as long as they have the necessary information.</p>	<p>they will not be obliged to request it in order not to affect the free movement of people within countries.</p>
<i>Trust Framework</i>	<p>A valid, secure, and interoperable barcode must be issued among all countries.</p>	<p>The domestic use of any of the 3 certificates is not prohibited for events, work, or public transportation. For this purpose, each of the countries must introduce this restriction within their own legislations. However, they must guarantee that certificates issued before that will continue to be valid.</p>
<i>Trust Framework</i>	<p>To guarantee interoperability with international regulations or technology systems.</p>	<p>All countries must have a guarantee that the certificates they issue digitally will be able to interoperate with the countries belonging to the connectathon in accordance with existing guidelines.</p>
<i>Revoked</i>	<p>It should be possible to exchange information regarding the certificate revocation list, especially for those that have been issued incorrectly or fraudulently.</p>	<p>In addition to this, certificates must be revoked in the case of defective vaccine batches.</p>

COVID-19 Vaccination Certificate

Requirements

The following modifications³ have been introduced to the requirements specific to the vaccination certificates.

Requirement	Description	Modification
General	One certificate must be issued per person per vaccine, test, or recovery. The certificate must not contain information from previously generated certificates.	The vaccination certificate must include the total amount of doses that were administered to the certificate owner.

The certificate must include the total amount of doses administered to the person who owns the certificate. This number will vary depending on the type of vaccine, because there are vaccines which require one or two doses.

In addition, they must include the booster shot in case it has been administered. For the booster shot, the expiration deadline for the certificate must be extended for a period of time of 3 more months.

Certificates will be revoked if the last vaccine has been administered more than 270 days ago. These certificates will be added to the revocation list, and the person must be informed of the revocation in a timely manner. Therefore, the only valid certificates will be those that have not exceeded 270 days from the first date of vaccination.

In the case of individuals who have only received a single dose of the vaccine and who have contracted the COVID-19 infection, they must be able to enter the countries with the corresponding certificate.

Any person younger than 12 years of age who has received a dose of the COVID vaccine must present a valid vaccination certificate for cross-border travels.

³ Functional and Non-Functional Requirements for a Proof of Concept, page 15

COVID-19 Testing Certificate

The following is a description of the modifications applied to COVID⁴. testing certificates.

Requirements

Requirement	Description	Modification
General	Creating a list of PCR tests and of rapid antigen tests, which must be validated by all member countries.	Rapid antigen tests performed ONLY by healthcare or qualified personnel has been added to the list as a consequence of the lack of PCR tests.
General	New Req.	It must be valid to attach the HCID as a barcode to any paper certificate which has been issued to the ID for an individual.
General	New Req.	The DDCC generation service must accept data transferred from a connected and authorized LIS.
General	New Req.	Test certificates which include the minimum amount of data will need to include it in an HL7 FHIR format.
Identificación	The certificate must include data related to the certificate owner's identity among the personal data.	The DDCC must be responsible for issuing the HCID, since it can be associated with a person at the time of testing. It must be a unique HCID.
Verificación	New Req.	SMS-based verification of alphanumeric HCID can be provided by a PHA as a means to send a verification request. Otherwise, they will be able to receive a response with a status code.

As a consequence of the Omicron wave, which caused a considerable increase in the number of infections, there was a world-wide decrease in the availability of COVID detection tests.

This was the reasoning behind reevaluating rapid tests to be added to the list of accepted tests for test certificates.

Rapid tests were therein enabled, but only when performed by a healthcare professional or a person qualified to do so, always while there is reduced availability of PCR tests. Once the availability of PCR tests has stabilized, rapid tests will no longer be considered valid.

⁴ Functional and Non-Functional Requirements for a Proof of Concept, page 18

In addition, in the case of rapid tests, only tests with nasopharyngeal samples will be accepted – no tests involving saliva, urine, or other samples will be accepted.

COVID-19 Recovery Certificate

Following is a description of the modifications introduced for recovery certificates⁵.

Requirements

Requirement	Description	Modification
General	The certificate must contain the date the positive result was detected using a COVID-19 infection test.	Rapid tests will be accepted ONLY if they have been performed by healthcare personnel or properly trained personnel. The use of this test will only be valid when there is a high volume of infection cases. Otherwise, they will not be valid for the recovery certificate.

Rapid tests will also be accepted for recovery certificates. In order to be included in the certificate, rapid tests will need to have a specificity higher than 98% to be authorized. However, they will need to be considered when the number of NAAT tests is limited; otherwise, they will still be invalid.

With the steep increase in the case of numbers due to the Omicron wave, antigen tests performed before 10/01/2021 will also be considered valid when the health situation is facing a new COVID-19 infection wave.

⁵ Functional and Non-Functional Requirements for a Proof of Concept, page 19

Updates to Non-Functional Requirements

The following is a description of the new Non-Functional requirements details in the second WHO⁶ document, which have been added to the previous document⁷.

Requirement	Description	Modification
Accessibility	New Req.	The solution must include people with disabilities, so they can access the certificates and not be excluded.
Security/Privacy	New Req.	The confidentiality of the data must be considered very carefully. When there is data present in shared environments, there should be a careful separation between the data in the system and the data stored in the other system.
Compatibility	New Req.	A feedback channel should be provided in order to gather information and technical support requests.
Compatibility	New Req.	Learning material should be provided to users regarding how the tools work.

⁶WHO – Digital Documentation of COVID-19 Certificates: Testing Results. Technical Specifications and Implementation Guidance. March 31st, 2022.

⁷ Functional and Non-Functional Requirements for a Proof of Concept, page 47

Glossary

DGC	Digital Green Certificate
EU	European Union
EHN	European Health Network
EUDCC	EU Digital Covid Certificate
HSM	Hardware security module
DGCG	Digital Green Certificate Gateway
1D	Unidirectional
2D	Bidirectional
DDCC	Digital documentation of COVID-19 certificates
DDCC:VS	Digital documentation of COVID-19 certificates: vaccination status
HCID	Healthcare identifier
ID	Identifier
PHA	Public Health Agency
NAAT Test	Nucleic acid amplification test (NAAT), such as polymerase chain reaction with reverse transcription (PCR-RT), loop mediated isothermal amplification (LAMP), or transcription-mediated assay (TMA) to detect the presence of ribonucleic acid ARN for SARS-CoV-2.
Rapid antigen test (RAT)	Test based on the detection of virus particles (antigens) via a lateral-flow immunoassay which provides results in less than 30 minutes.
Antibody testing	Laboratory test meant to detect if a person has developed antibodies for SARS-Cov-2, which indicates that the certificate owner has been exposed to SARS-Cov-2 and has developed antibodies, regardless of whether the person was symptomatic or not.
IHE	Integrating the Healthcare Enterprise
EHR	Electronic Health Record

IPS	International Patient Summary
ICC	International Chamber of Commerce
LIMS	Laboratory Information Management System

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