

Certification of Substances Department

HDE/CB

**PUBLIC DOCUMENT**

(Level 1)

**PA/PH/CEP (23) 50**

Strasbourg, September 2023

**Certification of suitability to the Monographs of the European Pharmacopoeia**

**Certificates of suitability: electronic signature features**

## 1. Background

On 1 September 2023, the European Directorate for the Quality of Medicines & Healthcare (EDQM) implemented the CEP 2.0. As of this date, certificates of suitability (CEPs) are issued as PDF certificates that contain an electronic signature. Certain letters and the Attestation of Inspection created as part of the CEP procedure will also carry an electronic signature.

It should be noted that the EDQM's electronic certificates and electronic signature have been tested using Adobe Acrobat Reader and some electronic signature features may not be available with other PDF readers.

## 2. Electronic signature: features

Each electronically signed CEP contains a qualified electronic signature from a trusted provider and is fully compliant with the eIDAS Regulation ((EU) No 910/2014).

The qualified electronic signature meets the following requirements:

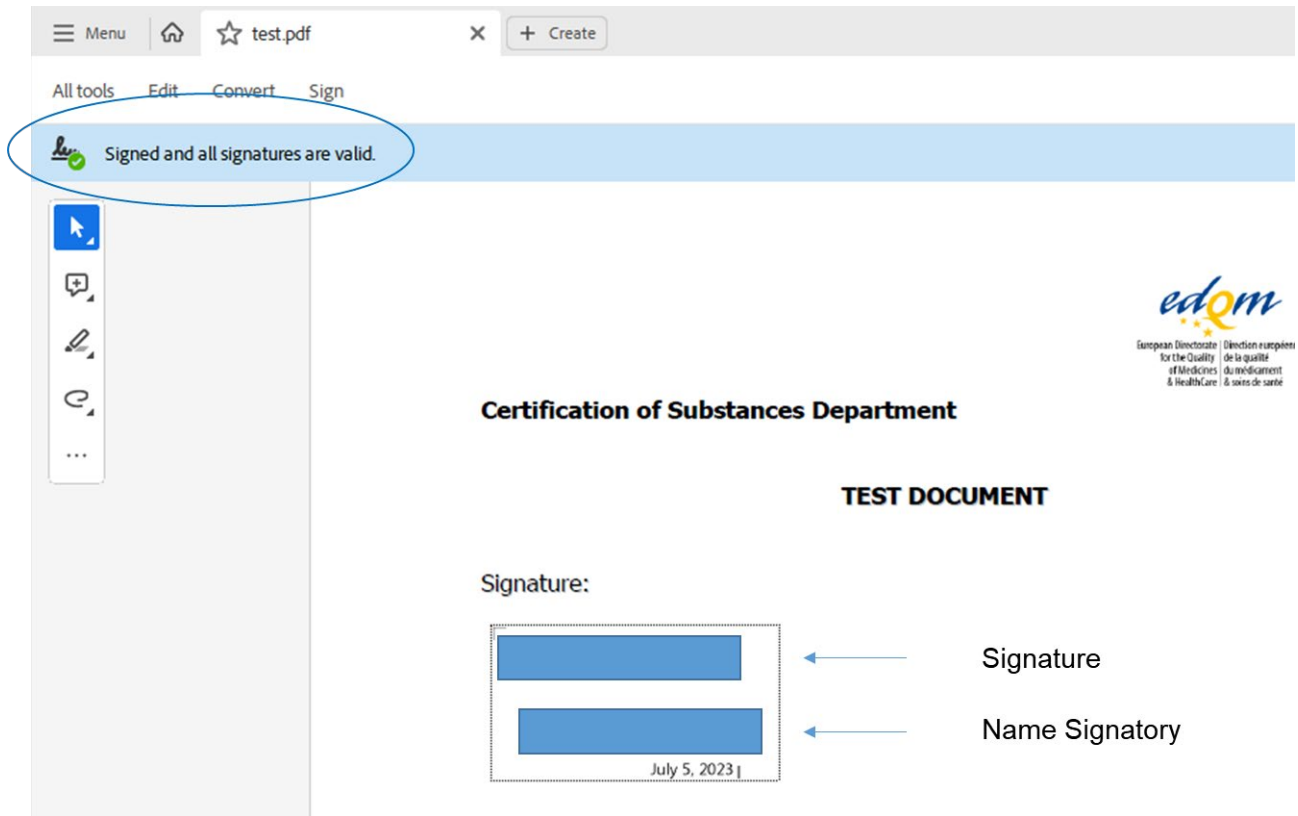
- it is linked to the signer;
- the signer can be identified;
- the document can only be signed by the assigned person;
- by certifying the PDF file, the CEP is locked and unauthorised changes will be detected;
- it uses a qualified signature creation device and relies on a qualified certificate for electronic signature provided by a qualified trust service provider;
- it has the same legal effect as a handwritten signature.

## 3. Signature validation

When opening the signed electronic document with Adobe Acrobat Reader, a signature panel ribbon will appear on the top of the document with a message bar to indicate the signature status (e.g. *"Signed and all signatures are valid"*).

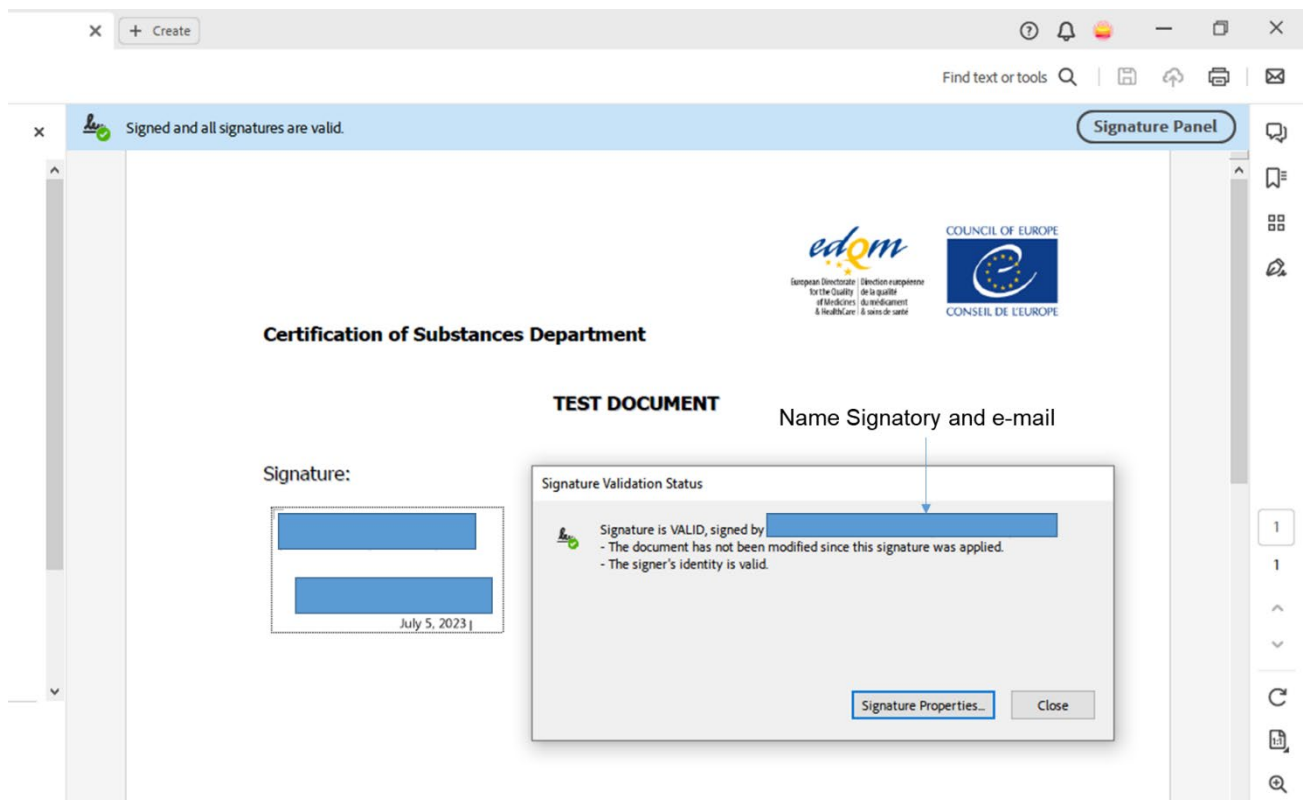
Signature validity is determined by checking the authenticity of the signature's digital ID certificate status and document integrity.

To do this, click on the electronic signature. The "Signature Validation Status" window will appear, stating the validity of the signature and the name and e-mail address of the signer; it also provides information on the history of the document since the first digital signature and time of signing, as well as trust and signer details.

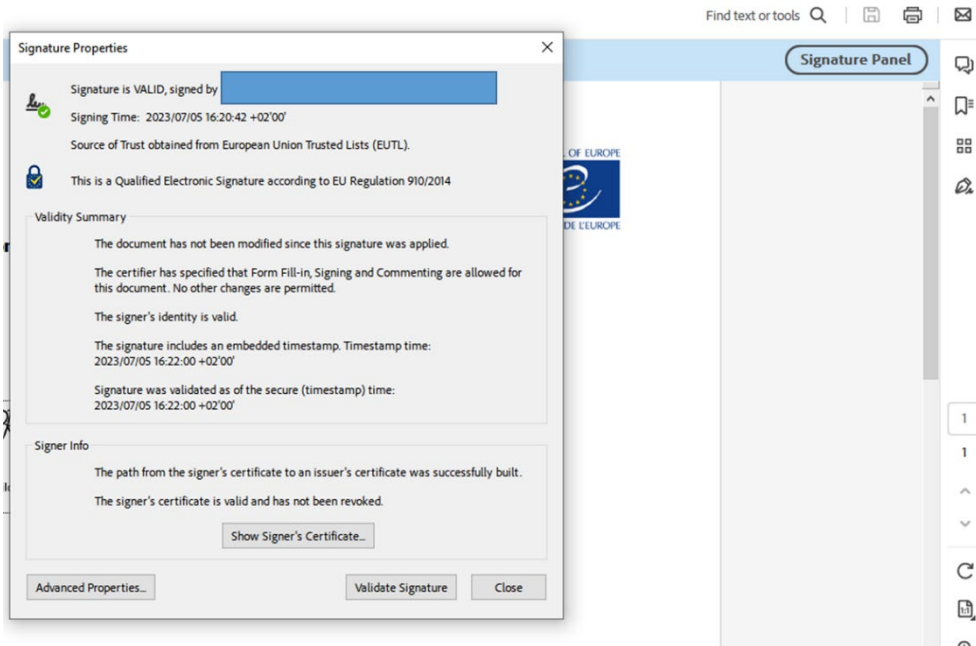


For documents with the “Signed and all signatures are valid” status:

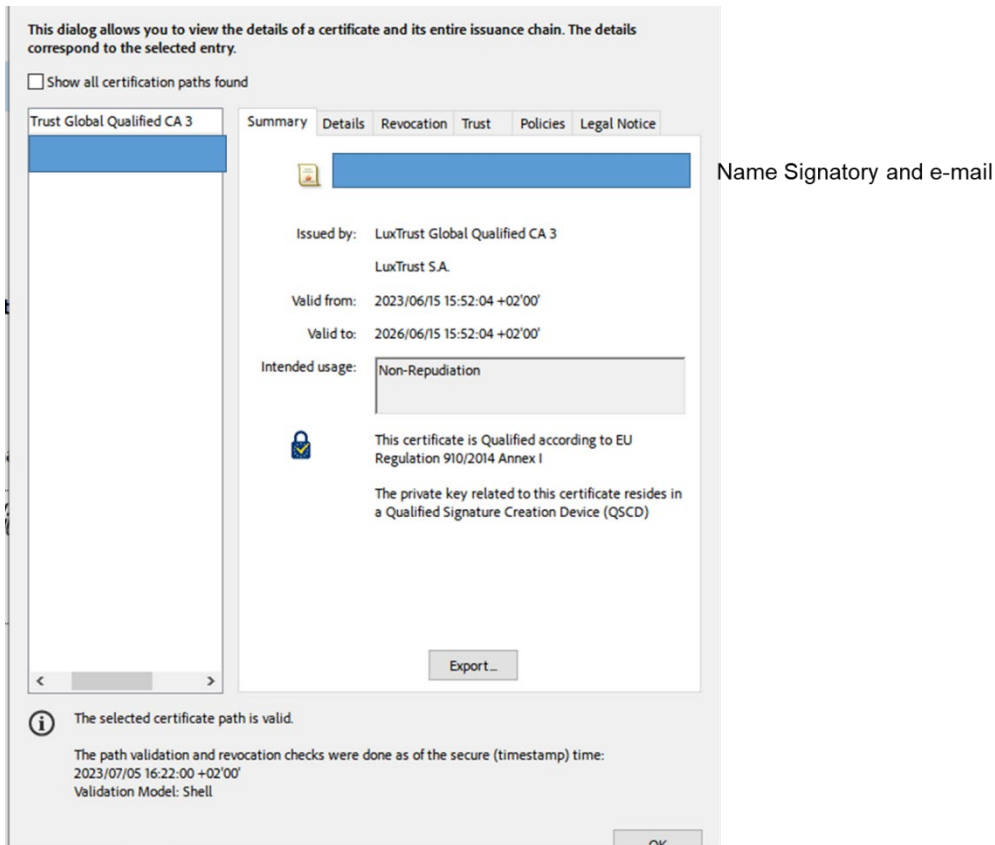
Click on the electronic signature. The “Signature Validation Status” window will appear, confirming that the signature is valid and stating the name and e-mail address of the signer, that the document has not been modified since it was signed and that the signer’s identity is valid.



When you click on the “Signature properties” button, a pop-up window will appear, confirming that the signature includes an embedded timestamp, that the signature was validated and that a path from the signer’s certificate to the issuer’s certificate was successfully established. This window also confirms the validity of the signer’s certificate.



Click on “Show Signer’s Certificate” to display the following window:

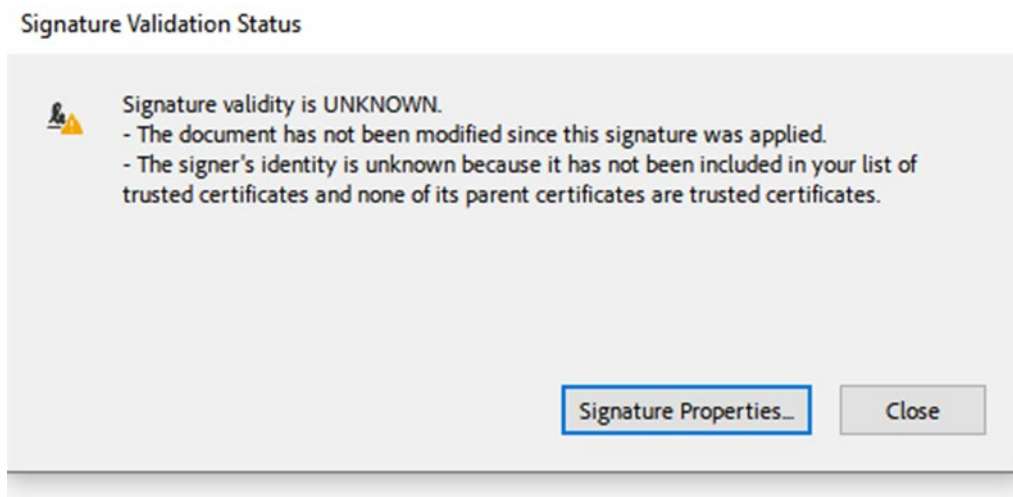


It should be noted that although the signer’s certificate shows a “Valid from” and “Valid to” date, these are unrelated to the validity of the CEP, which is displayed in the public CEP database.

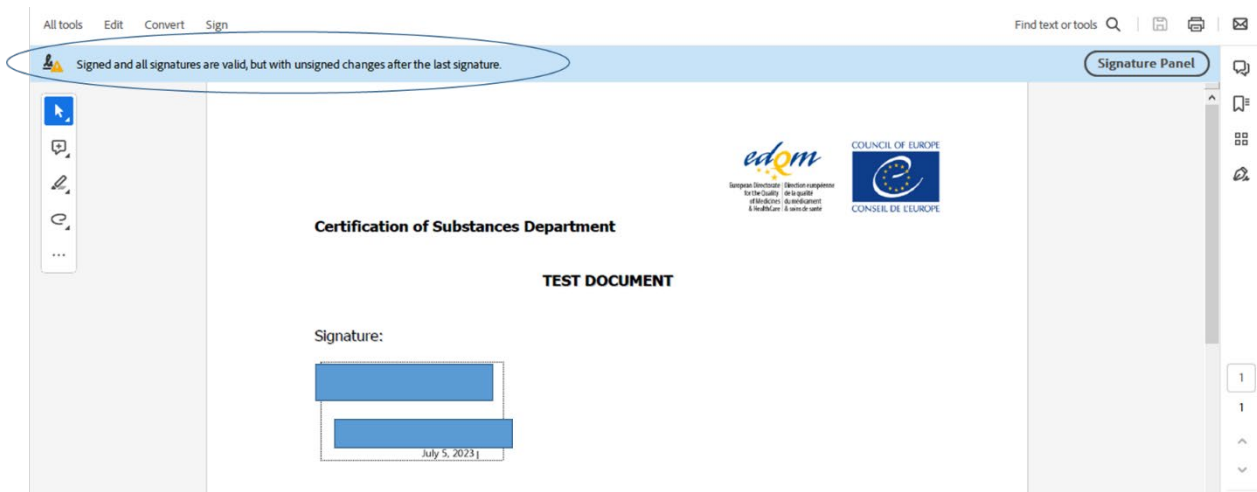
**For an invalid electronic signature or electronically signed document amended after signing:**

When opening an electronically signed document in Adobe Acrobat Reader where the signature is from an untrusted source, a signature panel ribbon will appear on top of the document with the message: "At least one signature has problems".

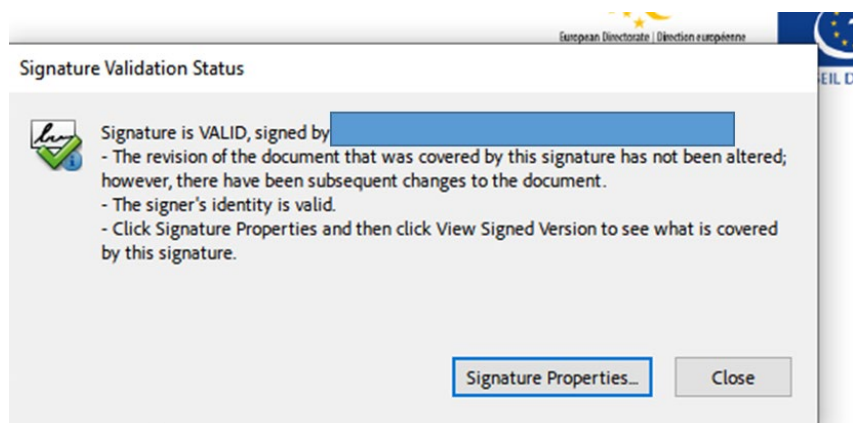
Click on the electronic signature. The "Signature Validation Status" will appear with a warning that the validity of the signature is unknown.



When opening a document that has been amended after being signed electronically, the following message is displayed in the signature panel ribbon:



Click on the electronic signature. The “Signature Validation Status” window will appear and display the following message:



In case of doubt about electronically signed documents, please contact the EDQM Certification of Substances Department via the [EDQM HelpDesk](#).