



European Commission

EUDAMED

European database on medical devices

The **notified body (NB)** shall enter EUDAMED any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be **accessible to the public**.

CERTIFICATE UNIQUE IDENTIFIER

How is a certificate identified?

CERTIFICATE PAPER VERSION UNIQUE IDENTIFIER

The paper Certificate version is identified by a unique number which is the "NB number + Certificate number (+ possibly 'Revision number')".



Current Actor in EUDAMED (Notified Body Identification number from Nando is automatically identified from user acting on behalf of NB.)

EUDAMED CERTIFICATE DATA VERSION IDENTIFICATION

The EUDAMED Certificate data version is identified by the "Certificate paper version unique identifier" and the "EUDAMED version number".



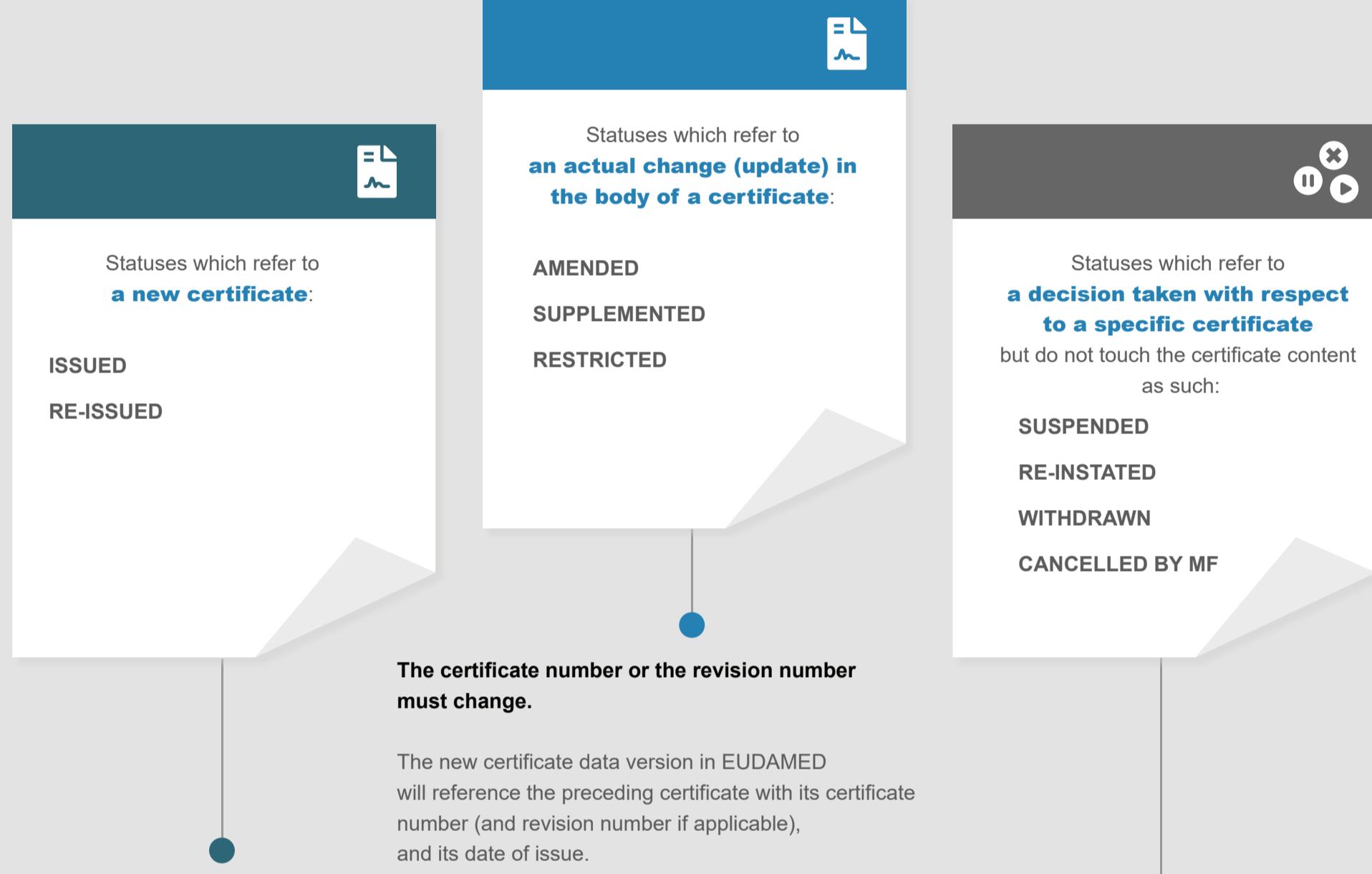
+

EUDAMED version number

The EUDAMED version number is incremented for any update of a certificate like for the certificate paper version identifier. However, in case of decision (Withdrawn, Suspended, Re-instated ...) applied on a certificate, it will mean a new EUDAMED version although not a new Certificate paper version.

STATUS OF CERTIFICATE

Status of Certificate and Certificate version identifier



The certificate number must be a new one.

However, in case of a RE-ISSUED certificate, the certificate number can be kept as it is for the preceding certificate only if a new Revision number is provided.

The certificate paper version identifier cannot change.

CERTIFICATE PAPER VERSION UNIQUE IDENTIFIER

Management of the paper Certificate version identifier

The **uniqueness of the certificate** identifier must be guarantee either only with a "Certificate number" or with both a "Certificate number" and "Revision number".

The second option allows to keep the same Certificate number across updates/re-issues.



NEW ISSUED CERTIFICATE



OPTION 1:



OPTION 2:



NEW PAPER VERSION

AMENDED, SUPPLEMENTED, RESTRICTED or RE-ISSUED



OPTION 1:



OPTION 2:

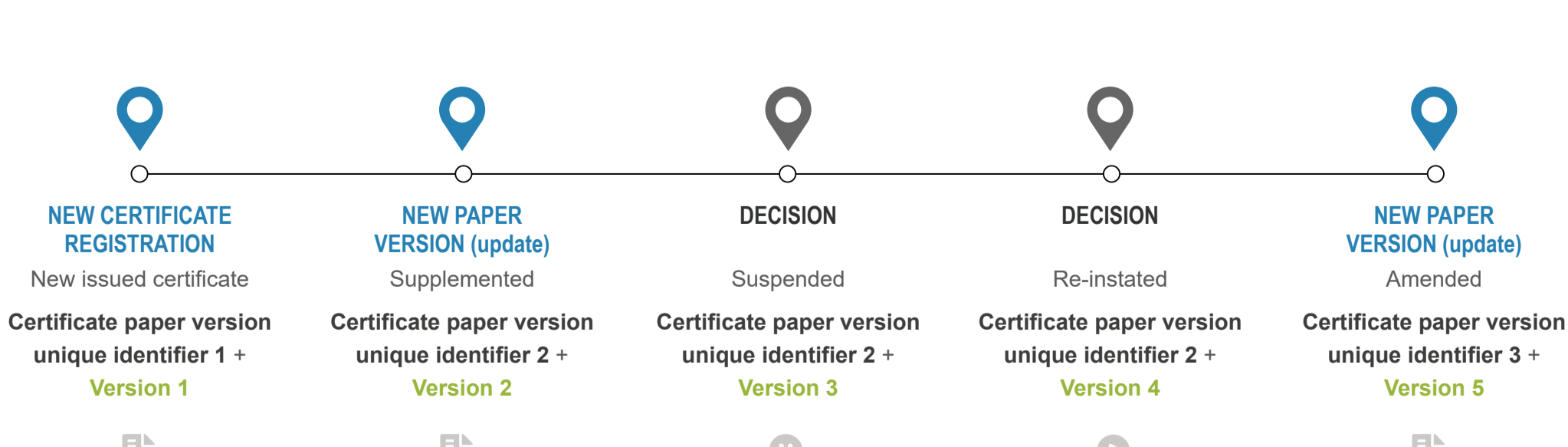


EUDAMED CERTIFICATE VERSION

Versioning of the certificate data in EUDAMED

EUDAMED will keep track of the historical data provided for the certificate registration/updates and decisions on the status of certificates.

Therefore, EUDAMED will always create its own version of the certificate data (incremental from 1 to n).



For each EUDAMED certificate version, several information will be stored among which the version number and the submission date.

