



European Commission

EUDAMED

European Database on Medical Devices

The notified body (NB) must enter any information into EUDAMED regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates.

Such information will be accessible to the public.

CERTIFICATE UNIQUE IDENTIFIER

How is a certificate identified?

CERTIFICATE PAPER VERSION UNIQUE IDENTIFIER

The Certificate paper 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 via the 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".



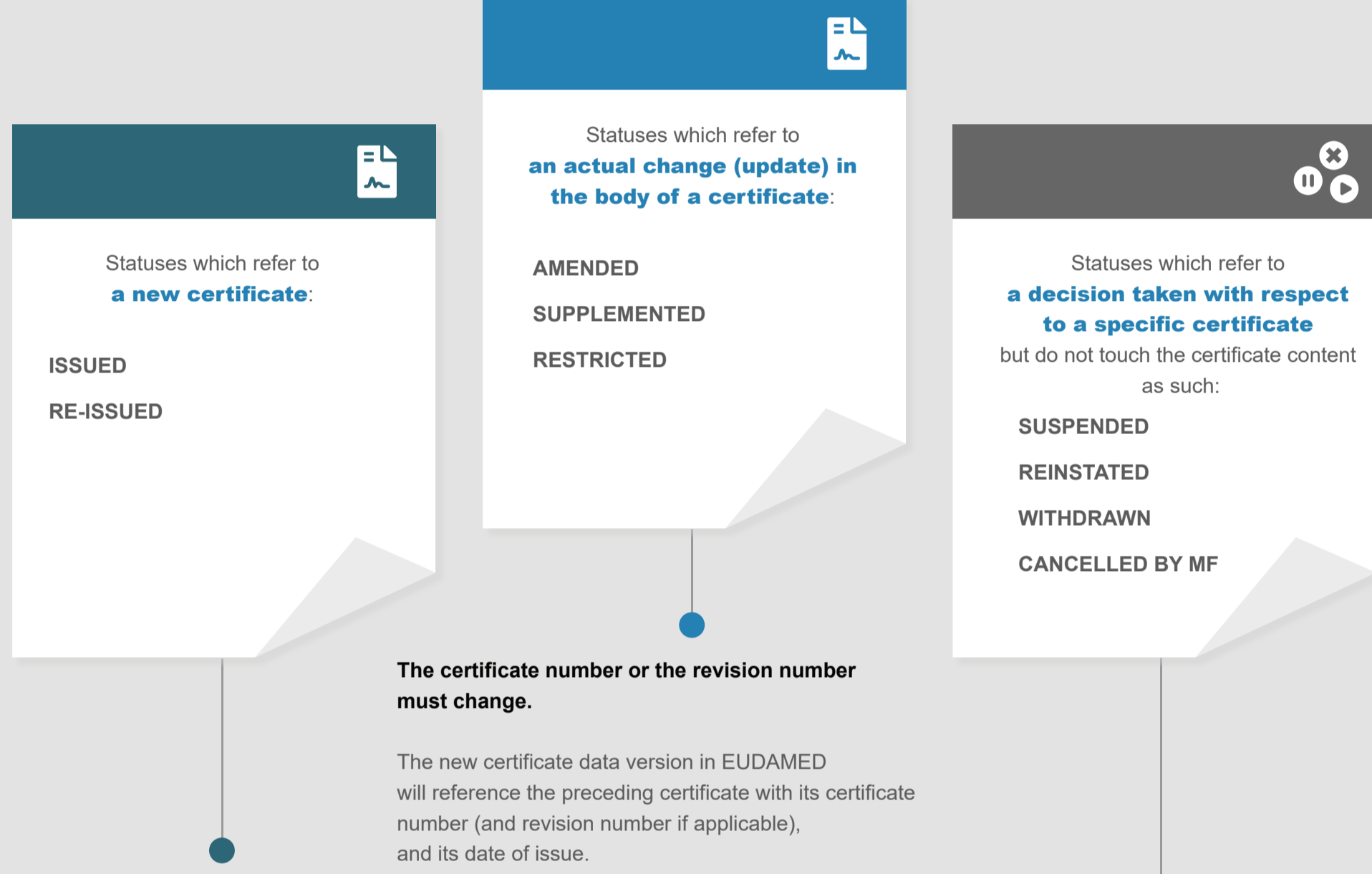
+

EUDAMED version number

The EUDAMED version number is incremented for any certificate update, the same as for the certificate paper version identifier. However, in the case of a decision being applied to a certificate (Withdrawn, Suspended, Reinstated...), this would mean a new EUDAMED version, although not a new Certificate paper version.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 the 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.

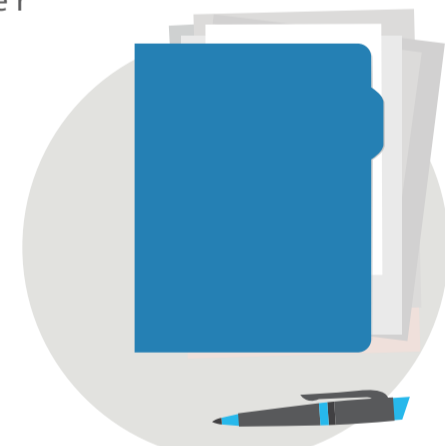
The certificate paper version identifier cannot change.

CERTIFICATE PAPER VERSION UNIQUE IDENTIFIER

Management of the Certificate paper version identifier

The uniqueness of the certificate identifier must be guaranteed with either a "Certificate number" alone, or with both a "Certificate number" and "Revision number".

The second option allows the same Certificate number to be kept across update/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 items of information will be stored, among which are the version number and submission date.

