

Submitting documentation to CE Certiso Kft.

Aim

Ensuring the appropriate management of client documentation. The certification and conformity assessment procedures performed by CE Certiso Kft. can only be carried out on the basis of the uploaded documentation, submitted by the clients in an appropriate manner and form.

Principles

CE Certiso Kft. is committed to the security of its clients' data. In order to ensure the security, traceability and closed handling of the data flow, CE Certiso Kft provides its clients a hyperlink for the submitting of each document, through which a secure upload can be conducted to a directory in the system of CE Certiso Kft.

- The documentation required for the certification and conformity assessment procedures can **only** be submitted by the clients **via the link** provided by CE Certiso Kft.

CE CERTISO KFT. DOES NOT ACCEPT ANY DOCUMENTATION SUBMISSION FROM CLIENTS VIA EMAIL, FILE SHARING HOST OR IN ANY OTHER FORM.

- Electronic file formats accepted by CE Certiso Kft:

Type of file(s)	Description	File extension
Text document	PDF (formatted) with embedded image(s) or other information. <ul style="list-style-type: none"> • <i>Searchability within the document must be ensured.</i> • <i>It is always necessary to create a table of contents for the documents.</i> • <i>If the document contains scanned parts, the text version (OCR program, etc.) must be inserted in addition to the original.</i> 	.pdf/.docx/.xlsx
Compressed container*	ZIP/RAR formatted, compressed collection of files: <ul style="list-style-type: none"> • <i>With no more subfolders than 5.</i> • <i>Where folder and file names cannot exceed the 60 number of characters.</i> 	.zip / .rar
List of uploaded documents	The list must contain all uploaded files in the same structure with the same names as the file names. <ul style="list-style-type: none"> • <i>The file name shall be identical to the name of the document, containing the version and/or date of the valid document in a consistent structure. (see: 4. Uploading files)</i> 	.pdf/.docx/.xlsx

- The size of an uploaded file **cannot exceed 2 GB**.
- *Folders can only be uploaded in a compressed form.
- Requesting the link is only applicable in case the documentation submission does not fall into the below listed categories.

A link will be provided without request in the following cases:

- stage 1 documentation for evaluation
 - MDR application
 - sharing documentation during the audit
 - a change notification (see: *0. Submitting a notification*)
-
- In case of each correction (e.g.: correction for application, audit or evaluation, etc.) the client shall request a link at least 5 working days before the deadline.
 - By initiating an upload, our clients acknowledge and accept the responsibilities, deadlines and resulting consequences of submitting files to CE Certiso Kft.

How can our clients submit the documentation required for certification and conformity assessment procedures to CE Certiso Kft?

0. Submitting a notification

In case the files are related to a change, before/instead of requesting a link, the client shall submit a change notification form to the notification@cecertiso.hu address.

(The valid form is always available at the website of CE Certiso Kft.)

After all administrative tasks are completed the client will be informed about the required documents and a link will be provided if the change can be accepted for evaluation.

1. Preparing documentation to be uploaded

We suggest, clients complete the following actions even before requesting the link and especially before starting an upload to ensure a correct submission:

- ✓ compile material in a folder on your own device,
- ✓ make sure that only one copy of each file is included (the current, valid version)
- ✓ check file names (so they do not contain old, accented letters or special characters)
- ✓ check if the file names are the same as the name of the document
- ✓ create a detailed document list (with exact file name, document version and date)
- ✓ check by the document list that everything is included, and the versions/dates are also correct
- ✓ create a (zip or rar) compression of the folder/files
- ✓ make sure that the size of each file does not exceed 2 GB,
- ✓ check your internet connection to see if it is suitable for uploading at the right speed, if not, look for another connection point

2. Request a link

To request a link, the client must indicate the following, according to this example:

- **name of the organization** *XY Ltd.*
- **the description of the related process:** *Surveillance conformity assessment procedure according to Annex IX of MDR*
- **subject of upload:** *correction of nonconformity*

Upload link can be requested at the link@cecertiso.hu e-mail address by providing at least the above listed information.

3. Providing an upload link

- In case of a correct request and no obstacles (e.g.: unpaid invoice), CE Certiso Kft will provide an upload link for the client within 5 working days.
- **Via the link (if other deadline that was agreed on does not overwrite this) the client must submit the documentation within 10 days, also complying with the instructions sent with the link.**
- The link has a general 10-day-validity; however, it cannot exceed 30 days in any case, therefore the client shall take this into consideration when requesting a link for an upload with an extended deadline.
- In case the intended date of the upload extends the default 10 days of the validity, the client must include the required validity of the link in their request. (Max. 30 days)
- In case the client does not upload the content within the validity of the link, the further request regarding the same subject will be considered as correction for the same upload.
- In case the client does not upload the content within the validity of the link and does not request a new link for the corrective upload within 5 working days CE Certiso Kft will provide a new link (if the procedure deadline makes it possible) with the default validity.

4. Uploading files

For each upload, the client must attach an accurate document list to the notification email (5) about the uploaded documents. The document list shall include:

- ✓ Number of uploaded documents (in total).
- ✓ All documents to be submitted must be listed.
- ✓ The list must contain all uploaded files in the same structure with the same names as the file names.
- ✓ For each document: the exact file name, document version or date.
- ✓ The file name shall be identical to the name of the document, containing the version or date of the valid document in a consistent structure.

In case the folder or files names had to be shortened for the upload, the list can include the intended or original full names but only if the actual uploaded names are also referenced or marked properly.

The client should only start uploading if the document list is available.

5. Client's notification email (to CE Certiso) on the upload

It is the responsibility of the client to inform in response to the previously received email (which contained the link, to the link@cecertiso.hu address) within 1 workday after the upload the following:

- if the files were uploaded successfully, or
- if the upload was unsuccessful.

In case of successful upload, the email shall contain the list of the uploaded documents.

Without the email notification the upload cannot be considered valid.

After a positive feedback from the client, CE Certiso will close the link regardless of the previously set validity of it.

6. Checking the uploaded files

CE Certiso Kft. will check in all cases:

- availability of the list of uploaded documents
- the receipt of the files (in case of every document) sent by the client according to the list of documents
- if the main compressed file(s) can be opened or not

The content and the conformity of the files is not reviewed by CE Certiso Kft. at this point, it is done during the certification and/or conformity assessment procedure.

If the procedure deadline allows it, **one upload can be corrected 3 times.**

At the 3rd time the upload will be considered as the final and valid submission and the client is notified of the uploaded list of files (with a print screen image) that this content will be forwarded for evaluation. It is a round of correction if the list of the uploaded documents is not attached.

7. Feedback

CE Certiso Kft. sends a feedback on the submitted documentation's receipt in every case, within 5 working days.

This feedback is only an administrative task of checking the list of files, whether all intended files were successfully uploaded according to the table of content that was attached to the upload.

The acceptance of the upload is not equal to the review of the application and it does not involve any feedback on the content of the documents.

Our clients are kindly requested to contact us via info@cecertiso.hu in this matter only if they do not receive any feedback on the upload within 5 workdays or in case of any question regarding the submission process.

Please note, that the confirmation email should be kept for your own benefit, as it can later prove the successful uploading of the documents!