# Customer documentation management

Written by:

Dr. Mikulásik Endre

Quality Expert

Checked by:

Szájer Erika

Quality Manager

Approved by:

László Imre

Managing Director

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## 1. Purpose, scope

Ensuring proper management of customer documentation. The certification and conformity assessment procedures carried out by NEOEMKI can only be carried out on the basis of uploaded documentation duly submitted by the customer in the appropriate form and manner. The submitted documents are official and form part of the certification and/or conformity assessment procedure and therefore both the uploader and NEOEMKI are responsible for them.

## 2. Definitions, acronyms

| | |
|---|---|
| Customer (organization, commissioner, applicant, manufacturer) | A natural or legal person who has a contract with NEOEMKI to perform certification and/or conformity assessment activities. |
| Customer documentation | The quality management and/or product documentation (e.g. quality manual, technical documentation, etc.) to be provided by the customer for the certification and/or conformity assessment procedure. |

## 3. Principles

- Customer documentation for certification and conformity assessment procedures can only be submitted to NEOEMKI **via the upload link** provided by NEOEMKI.

  **NEOEMKI does not accept documentation by e-mail, file sharing or any other means!**
- NEOEMKI is committed to keeping customer data secure. To achieve this, to ensure the security, traceability and confidentiality of data flows, each time a document is requested for upload, an upload link is sent to the customer by email, allowing them to upload documents directly and securely to the NEOEMKI system library.
- The customer relevant parts of the procedure will be published on the NEOEMKI website and may also be made known to the customer by other means (e.g.: informational e-mail, etc.).
- For each upload, the customer must attach an accurate list of documents uploaded in accordance with this procedure.
- **Electronic document formats accepted by NEOEMKI:**

| File type(s) | Nature of the document | File extension |
|---|---|---|
| Office documents | Text document, spreadsheet document, presentation with embedded image. All of these documents can only be uploaded in Portable Document Format (pdf) version.<br>Software searchability within the document must be provided.<br>In all cases, a table of contents must be provided for the documents. If the document contains scanned parts that are not searchable, a textual version converted by customer (with OCR, transcription, etc.) must be included alongside the original. | .pdf |

| File type(s) | Nature of the document | File extension |
|---|---|---|
| Compression | ZIP format compressed file, which cannot contain more than 5 subfolder levels.<br>Folder or file names must not exceed 60 characters.<br>Folders can only be uploaded in compressed format. | .zip |
| List of uploaded documents | The list of uploaded documents is part of the documentation, therefore each document must have an identifier (version, date). In the list, the document must be identifiable and interpretable from the filenames, showing the version and/or date of the uploaded documents in a consistent structure.<br>(e.g. ”Risk_Management_File_v01_02_03_2025”). | .pdf |

- The total size of the uploaded files must not exceed 2 GB.
- In case the files are related to a change, before or instead of requesting the link, the customer must submit a change notification form (in the area of system certification, MDD, IVDD: **M10-N** Change Notification Form, in the area of MDR: **F8915-N** Change Notification) to the e-mail address cert@emki.hu. Once all the administrative tasks have been completed, the customer should be informed of the documents to be submitted if they are necessary for the assessment of the change.
- The request for a link is only necessary if the submission does not fall into one of the categories listed below.

  The link is provided without the customer's request in the following cases:
  - uploading the stage 1 documentation
  - MDR application (request)
  - sharing documentation during the on-site audit
  - in case of a change notification.
- In case of submission of documents related to corrections (e.g.: gap filling for application, corrections of audits and evaluations, etc.), the customer must always request an upload link at least 5 working days before the deadline.
- By initiating an upload, our customers acknowledge and accept the responsibilities, deadlines and consequences of submitting files to NEOEMKI.

## 4. Responsibilities

| Task | Responsible person/organization |
|---|---|
| Informing customer on the customer documentation management process. | Quality Administrator (NEOEMKI) |
| Creating and sending a link to the customer. | Quality Administrator (NEOEMKI) |
| Downloading and checking the documentation submitted by the customer (completeness of files, openability). | Quality Administrator (NEOEMKI) |

| Task | Responsible person/organization |
|---|---|
| Sending confirmation of the upload to the customer (in case of error, requesting the correction and checking the corrected files). | Quality Administrator (NEOEMKI) |
| Closing the link. | Quality Administrator (NEOEMKI) |
| Notifying auditors, product reviewers, clinical experts of the receipt of documents. | Quality Administrator (NEOEMKI) |
| Requesting a link, preparing and uploading customer documentation, sending a notification of the upload (by email). | Customer |

## 5. Process

**How can customers submit documentation for certification and conformity assessment procedures to NEOEMKI?**

- **Step 1**: **Preparing to upload**

  Customers are advised to perform the following actions before starting the process in order to ensure a flawless upload:

  - ✓ compiling documentation on your own computer in a folder, making sure that the folder contains real files, not just shortcuts,
  - ✓ checking that there is only one copy of each file (preferably the valid or latest version),
  - ✓ checking the portability of filenames (without accented letters and special characters),
  - ✓ creating a table of contents/document list (exact file name, version and/or date),
  - ✓ checking based on the table of contents/document list to make sure that everything is there and that the versions/ dates are correct,
  - ✓ creating a compressed file (zip) and naming it as follows: name + date and/or version, making sure that the total size of the material to be sent does not exceed 2 Gb,
  - ✓ checking your internet connection to see if it can handle uploads at the right speed, if not, find another connection point.

- **Step 2: Requesting an upload link**

  It is initiated by the customer by indicating the purpose. To request a link, the customer must specify the following:

  - the name of the customer concerned (e.g. XY Ltd.), the name and contact details of the sender,

- name of the procedure concerned (e.g.: initial conformity assessment procedure of XY Ltd. according to Annex IX of the MDR, surveillance procedure of XY Ltd. according to the standard EN ISO 13485:2016, etc.)
- the exact purpose of the upload (e.g.: submission of documentation for MDR application, quality management system documentation, full technical documentation for XY product, correction of non-conformity, etc.)

Upload link can be requested by emailing cert@emki.hu and providing the full details above.

- **Step 3: Sending an upload link**

  If the request is valid, NEOEMKI will provide the customer with the upload link within **5 working days**. The customer has a maximum of **10 days** to submit the documentation via the upload link (unless overridden by other agreed deadlines), based on the instructions provided with the link.

  The validity period of the link is **10 days** by default. In justified cases, a longer period may be granted by prior agreement, but in no case may it exceed **30 days**.

  In the case that the basic 10 days of link validity needs to be extended due to the planned date of upload, the customer must request this, indicating the desired validity of the link upload. This extension may be up to **2 working days** in any one case.

  In the event that the customer does not upload the content during the validity period of the link, a further request for the same subject matter will be considered as a correction for the same upload.

- **Step 4: Uploading**

For each upload, the customer must attach a precise list of documents uploaded in accordance with this procedure. The document list shall include:

- ✓ Number of documents uploaded (total). All documents to be submitted must be indicated in the list.
- ✓ For each document, the exact file name, document version and/or date.

The customer should only start uploading if the document list is available and attached in a verified manner.

- **Step 5: Sending a notification of upload**

  It is the customer's responsibility to indicate the following in response to the email (in which the link was sent) received previously, preferably within **1 working day** of uploading:

  - if they have successfully uploaded the files, or
  - if the upload failed.

In the absence of an e-mail notification, the upload will not be considered valid even if it has been carried out physically.

**After positive feedback, NEOEMKI will close the link regardless of the previously set validity.** ***There is no possibility of subsequent exchange or modification of uploaded files, they will be handled as part of a change, if justified.***

There is no possibility of partial uploads or uploads in several instalments. The documentation on the link is considered final at the time of closing the link.

- **Step 6: Verification**

  NEOEMKI checks in all cases:

  - the availability of the uploaded list of documents. ***If there is no document list, the upload will be considered invalid.***
  - the availability of the submitted files (whether all files are present) according to the list of documents submitted by the customer, and
  - the openability of the compressed documents.

  The contents of the files are not checked by NEOEMKI at this stage, this is done at a later stage of the certification and/or conformity assessment procedure.

  **An upload can be repeated 3 times if it was unsuccessful!**

- **Step 7: Confirmation**

  In all cases, NEOEMKI will provide feedback on the receipt of the submitted documentation within **5 working days**.

  Feedback will also be sent if the upload is unsuccessful, invalid or the link is closed. In all cases, the reason for the invalidity must be indicated in the feedback (e.g. part of the documents cannot be opened, or the list of documents submitted does not match the uploaded files, etc.)

  We ask our customers, if you do not receive a confirmation from NEOEMKI within 5 working days from the upload notification, please contact cert@emki.hu!

  Please note that it is in your own best interest to keep the confirmation email, as this will allow you to verify the successful upload of documents in the future!

  At the same time as the confirmation, the Quality Administrator (NEOEMKI) sends a notification of successful upload to the auditors, product reviewers and clinical experts involved in the project.

  This confirmation is an administrative task only. Its purpose is to ensure that NEOEMKI is confident that all the planned files have been successfully uploaded according to the document list attached to the upload.

  Acceptance of an upload does not imply an evaluation of the content of the submitted documentation.

## 6. Document changes

| date | edition | version | modification | justification |
|---|---|---|---|---|
| 2022.02.25 | 01 | 01 | Issuing a new procedure. | Procedure for designation under MDR, IVDR |
| 2024.10.09 | 01 | 02 | Chapters 3 and 5: Modification of accepted electronic document formats. | NEOEMKI has been designated as the notified body for conducting conformity assessment under MDR (Regulation (EU) 2017/745 on medical devices). Complete review of procedure. |