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European Medicines Agency

Working instructions for Notified Bodies on the application of Article 54 of Regulation (EU) 2017/745 on medical devices and Article 48 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Expanded document D 5.1

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1. Purpose of this document

The purpose of this document is to describe the main steps to be followed by notified bodies (NBs) during the expert panel consultation procedure foreseen in:

- **Article 54 of Regulation (EU) 2017/745 on medical devices (MDR)**¹, i.e., the clinical evaluation consultation procedure (CECP) for specific high-risk devices, which may result in the provision of an expert panel opinion on specific aspects of the notified body (NB)'s clinical evaluation assessment report (CEAR).
- **Article 48 of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)**², i.e., the performance evaluation consultation procedure (PECP), in certain cases, for class D devices, leading to an expert panel's view on the manufacturer's performance evaluation report (PER).

The document provides practical information on how to handle these steps (e.g., on IT tools) and refers to the main guidance documents to be consulted during the procedures.

2. EXPAMED and its Secretariat

2.1. EXPAMED

The medical device Expert panels (EXPAMED) have been designated by the Commission Implementing Decision (EU) 2019/1396 in relevant medical and technological fields³:

- 11 specialised thematic expert panels (10 for medical devices and one for *in vitro* diagnostic medical devices);
- 1 screening panel, and
- 1 coordination committee.

Expert panels are structured into sub-groups based on considerations such as specific device technologies or applications within one medical field.

2.2. EXPAMED Secretariat

The Commission Implementing Decision (EU) 2019/1396 establishes a secretariat for the expert panels (the "Secretariat"), whose main function is to coordinate the efficient functioning of the panels and to provide support to the expert panels. Additional Secretariat functions concern the management and prevention of potential conflicts of interest, supervision of the decision by the screening panels, ensuring transparency in regard to panel operations by publishing relevant expert information, as well as expert advice, and, where applicable, justifications by NBs in case the NB has not followed expert advice.

The Regulation (EU) 2022/123⁴ has given the European Medicines Agency (EMA) the mandate to provide the EXPAMED Secretariat on behalf of the Commission.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745>

² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746>

³ [EUR-Lex - 32019D1396 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1396)

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0123>

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2.3. EXPAMED Secretariat

The Secretariat ensures and supports efficient document management and is the main interlocutor of both NBs and EXPAMED experts for CECP and PECP.

For any questions, NBs may contact the EXPAMED Secretariat at the following email address:

[EU-OPERATIONS-EXPAMED\(at\)ema.europa.eu](mailto:EU-OPERATIONS-EXPAMED(at)ema.europa.eu)

3. The CECP: step-by-step workflow for NBs

Article 54 of MDR outlines a mandatory clinical evaluation consultation procedure (CECP) for implantable class III devices and class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12), unless specific exemption criteria are fulfilled (MDR Article 54(2)).

For the aforementioned mentioned medical devices, the CECP is part of the conformity assessment.

Figure 1 gives an overview of the CECP’s actors, steps, decision nodes, criteria, as well as timelines.

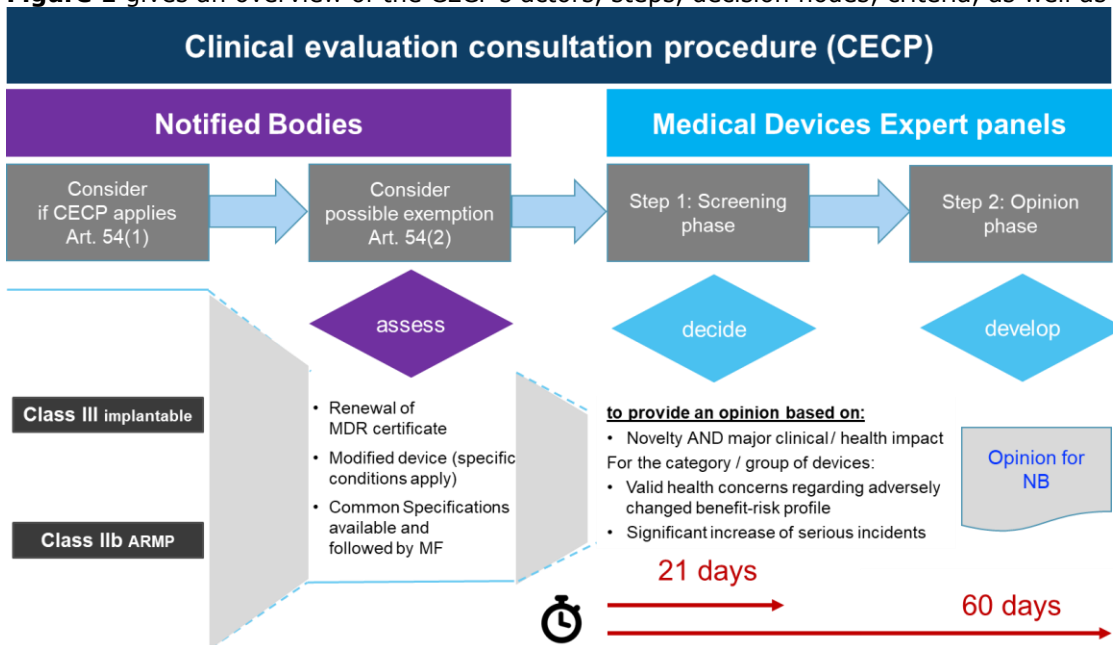


Figure 1: Schematic overview of the CECP

The practical steps to be followed by the NB during the CECP and the subsequent notification to be sent by the NB to competent authorities in support of the mechanism for scrutiny (MDR Article 55) are summarised in **Figure 2**. These **NB steps** are then described in detail in the next sections (NB steps 1 to 7).

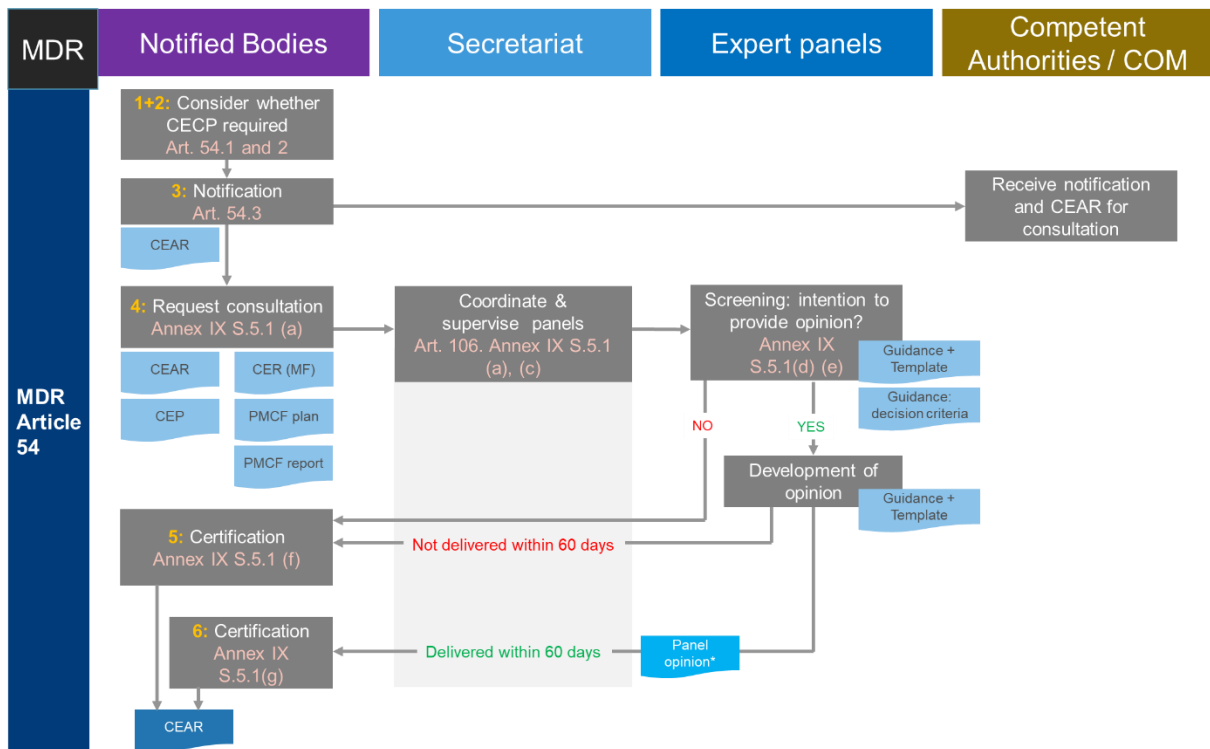


Figure 2: Schematic workflow of the NB action in regard to Article 54 (CECP)

3.1. CECP step 1: does the device qualify for CECP?

As a first step, the NB needs to consider whether the device under evaluation falls into the risk classes and types (Article 54(1)) that qualify for consultation by expert panels in regard to aspects of clinical evaluation assessment, i.e., class III implantable medical devices and class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12).

3.2. CECP step 2: does the device require CECP?

If the qualification criteria are fulfilled, the NB then needs to consider the three exemption criteria described in Article 54(2) of the MDR. The CECP is not required if any of these 3 criteria are fulfilled:

- (a) in the case of renewal of a certificate issued under this Regulation;
- (b) where the **device has been designed by modifying a device already marketed** by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device, see also MDCG 2019-3⁵; or
- (c) where the **principles of the clinical evaluation of the device type or category have been addressed in a CS** referred to in Article 9, and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device.

With regard to exemption criterion (c) on the use of Common Specification (CS), the NB needs to confirm that the clinical evaluation of the MF for this device is in compliance with the relevant CS for clinical evaluation of that kind of device. This confirmation will be documented by the NB (in

⁵MDCG 2019-3 (https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_3_rev1_cecp_en_0.pdf)

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accordance with Section 4.6 of Annex VII) in the CEAR that will be made available to competent authorities in accordance with Article 54(3).

3.3. CECP step 3: notification in regard to whether or not the CECP is to be applied

Having considered the qualification criteria (section 3.1) and the exemption criteria (section 3.2), the NB needs to notify the competent authorities, the authority responsible for NBs and the Commission whether or not the CECP is to be applied (MDR Article 54(3)).

3.4. CECP step 4: request consultation by uploading the dossier on CIRCABC

In case a device qualifies and requires a CECP, the NB must follow the procedure outlined in MDR Annex IX Section 5.1 (also referenced in Annex X, Section 6) and needs to transmit the CECP dossier via a secure system to the Secretariat.

3.4.1. Documents to be included in the CECP dossier:

The CECP dossier should include the following documents:

- the completed metadata template⁶
- the CEAR;
- the clinical evaluation plan (CEP);
- the clinical evaluation report (CER);
- the post-market clinical follow-up (PMCF) plan;
- the PMCF evaluation report, where available.

For a detailed outline of the documents, please see **Annex I**.

3.4.2. Marking of all the documents according to the Commission marking instructions

The documents to be transmitted for expert consultations are likely to contain commercially confidential information and trade secrets. Within the Commission, such information is considered "sensitive non-classified" (SNC), and there are specific rules for the handling of such information by Commission and external experts, in particular to avoid that such information is accidentally divulged beyond Commission staff and experts. Notably, all experts are required to sign a declaration of confidentiality, which obliges them not to divulge any information that they have acquired in the course of their work as appointed experts.

In order to ensure awareness of the need to treat such documents with the necessary precautions, SNC information needs to be marked in agreement with the Commission Security Notice 1904 on "*marking and handling of sensitive non-classified information*". To this end security and distribution markings need to be inserted in the title part of individual electronic documents by the document proprietors.

⁶ **Expamed document D5.3:** Template for notified bodies: submission metadata and document checklist – Expert consultations clinical evaluation assessment and performance evaluation
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Since, for the purpose of the consultation, NBs are handling not only their own documents (CEAR) but also those of MF, NBs have the responsibility of ensuring that the MF's documents have been appropriately marked. To facilitate the work of NBs, specific marking instructions are outlined in a separate document⁷.

Briefly, NBs need to ensure that the documents listed above have the following markings on the front page (i.e., only one marking per document):

- the security marking SENSITIVE, and
- the distribution marking RELEASABLE TO EXPERT PANELS (EXPAMED).

This should be done before transferring the dossier to the Secretariat via a secure system. The Secretariat will check the accuracy of the markings. In case these are inaccurate, the NB will be requested to amend them.

Access to SNC documents within the handling entity is managed on a need-to-know basis in agreement with Security notice COM(2019) 1903. Further, concerning expert panels, in alignment with Security notice COM(2019) 1904, there are processes in place concerning which groups or persons within the expert panels are authorised to receive the documents. Importantly, all experts have signed a declaration of confidentiality.

3.4.3. Upload of documents on CIRCABC CECP Expert Panels Interest group

Once the documents have been appropriately marked, the NB needs to submit these in the secure system made available for the purpose.

The CIRCABC interest group must only be used for submissions of CECP or PECP consultation requests. It is located under the following link:

<https://classified.circabc.europa.eu/ui/group/313a8bbb-b442-4c04-a4d6-eb7bc78e323f>

To facilitate the work of NBs, specific instructions for transmitting documents in relation to a CECP dossier are outlined in a separate document⁸.

3.5. CECP step 5: consultation of screening panel and, where applicable, thematic expert panels

Following the upload of a new consultation dossier by a NB, the Secretariat will coordinate the consultation with the experts.

3.5.1. Responsibilities of the Secretariat prior to transmitting the dossier to the experts

While the Secretariat will make all reasonable efforts to transmit the dossier to the experts as soon as possible, it should be noted that there are various steps that need to be completed before. These include but are not restricted to:

- **checking the completeness of the dossier** in order to ensure that the experts will receive all the necessary information for their assessment and that the information presented is coherent and understandable. Completeness check may also include requests for clarification or missing

⁷ **Expamed document D5.2:** How to mark the documents to be transmitted to the Secretariat of the European Commission Expert Panels on medical devices and in vitro diagnostic medical devices (Expamed)

⁸ **Expamed document D5.4:** Instructions for transmitting documents in relation to a CECP or PECP dossier

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information whenever needed. If that is the case, NBs should replace in CIRCABC the initial submission by the updated one;

- **analysis of potential conflicts of interests (COI)** of experts in relation to a specific dossier and assignment of experts without COI to a specific dossier. This implies that the latest DOI is furnished and is complete;
- **communications with experts** determining their availability to work on a dossier and providing support throughout the procedure.

3.5.2. Coordination of the consultations by the Secretariat

The consultation will first involve two experts from the Screening Panel (Rapporteur and Co-Rapporteur), responsible for deciding whether or not there is intention to provide a scientific opinion. The screening experts base their decision on the application of three criteria outlined in MDR Annex IX Section 5.1. Guidance on the consistent interpretation of the decision criteria in the CECP is provided in the Commission guidance document 2020/C 259/02⁹."

NBs will be informed by email about the **timepoint** when the screening experts have received the dossier. NBs will be informed about the **result** of the panel consultations via upload of:

- the decision report of the screening experts in case no opinion is needed; in cases where an opinion is required the NB will be informed via E-Mail;
- the opinion report of the respective thematic panel or sub-group at the end of the process in case an opinion is needed.

During the consultation phase of the CECP, the NB may be requested to present its conclusions (see MDR Annex IX Section 5.1(b)) to the expert panel. In such cases, the Secretariat will inform the NB and arrange a meeting.

3.6. CECP step 6: consideration of the expert panel opinion in the conformity assessment by the NB

If an opinion is received within the 60-days timeline, the NB is obliged to give due consideration to the expert panel scientific opinion.

The NB shall, where applicable and as appropriate:

- advise the MF to restrict the intended purpose of the device to certain groups of patients or certain medical indications; and/or
- impose a limit on the duration of the validity of the certificate;
- advise the MF to undertake specific PMCF studies;
- advise the MF to adapt the instructions for use or the summary of safety and (clinical) performance (SSCP¹⁰); or
- impose other restrictions in its conformity assessment report.

NBs may decide not to follow the advice or to follow only part of it. In this case, it will need to provide a full justification outlining the reasons. The NB has to upload the justification on CIRCABC by using

⁹ [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0807\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0807(01))

¹⁰ Note that, in Annex IX Section 5.1 point (g) the MDR erroneously refers to the SSCP as 'summary of safety and performance, i.e., omitting the term 'clinical'

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the relevant reporting template¹¹. Both the panel opinion and the NB justification will be published on the website for expert panels.

4. The PECP: step-by-step workflow for NBs

Article 48 of IVDR on *in vitro* diagnostic medical devices (IVDR) outlines a performance evaluation consultation procedure (PECP) for class D devices other than devices for performance study. The PECP represents a specific part of procedures requested for conformity assessment of certain *in vitro* diagnostic medical devices. **Figure 4** provides a schematic outline of this procedure.

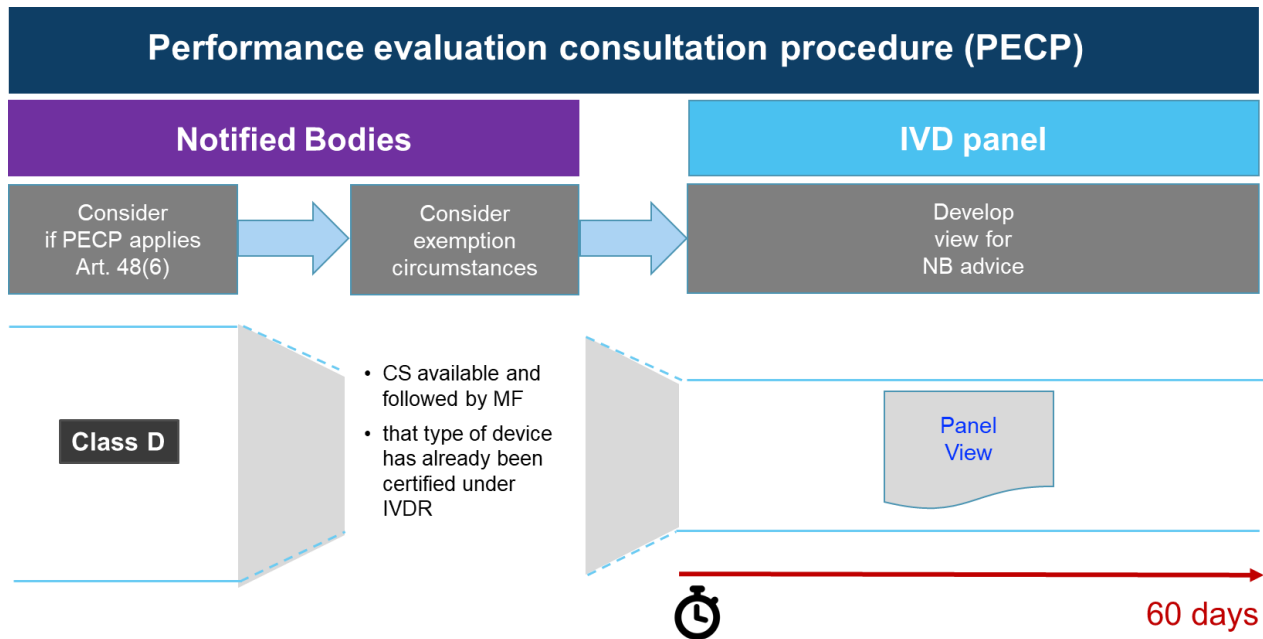


Figure 4: Schematic overview of the PECP

As part of this consultation, the notified body should consult the expert panel on the performance evaluation report (PER) of the manufacturer **if the following conditions are both fulfilled:**

- there are no common specifications (CS) available for the respective class D device **and**
- it is the first certification for *that type* of device under IVDR, see also MDCG 2021-22¹².

¹¹ **Expeded document D5.5:** Reporting template for notified bodies: completion of conformity assessment and justification

¹² https://health.ec.europa.eu/system/files/2022-09/mdcg_2021-22_en.pdf

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Figure 5 shows the various steps to be followed by the NB during the PECP application as well as the subsequent notification to be sent by the NB to competent authorities in support of the mechanism for scrutiny (IVDR Article 50). These NB steps are described in detail in the next sections (NB steps 1 to 5).

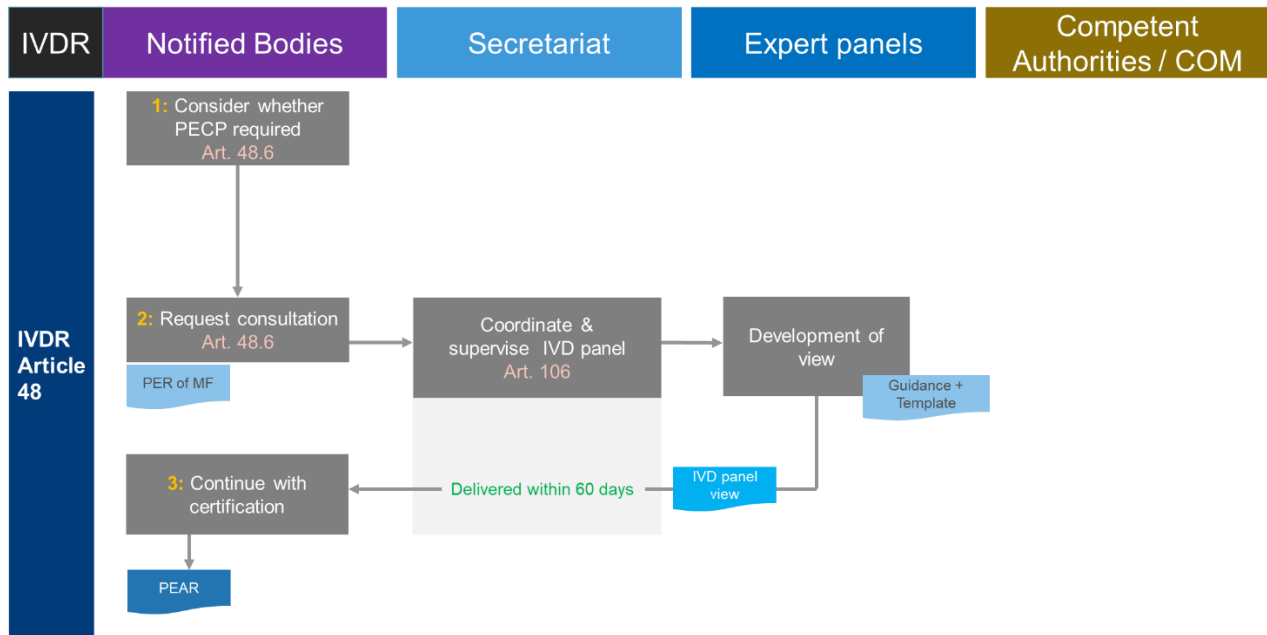


Figure 5: Schematic workflow of the NB action in regard to IVDR Article 48 (PECP)

4.1. PEPC step 1: does the device qualify for PECP?

As a first step, the NB needs to consider whether the *in vitro* medical device (IVD) under evaluation qualifies for a consultation by the IVD expert panel, i.e., if it is a class D IVD, as referred in IVDR Article 48(6).

4.2. PECP step 2: does the device require PECP?

IVDR Article 48(6) establishes the two conditions to be applied by the NB to determine whether it should consult the IVD panel on the performance evaluation report (PER) of the MF. The document MDCG 2021-22¹³ outlines the meaning of “first certification of that type of device”, how to determine this situation and which practical procedure to follow in regard to the initiation of the PECP. It also clarifies the term “available” with respect to common specifications.

4.3. PECP step 3: request consultation by uploading dossier on CIRCABC

In case a device requires PECP, the NB must follow the procedure outlined in IVDR Article 48(6) and Annex IX Section 4.9 and needs to forward the PER¹⁴.

4.3.1. Documents to be included in the PECP dossier

The PECP dossier should include the following documents:

¹³ https://ec.europa.eu/health/system/files/2021-08/mdcg_2021-22_en_0.pdf

¹⁴ To ensure that the experts have all available information, it is encouraged to submit the latest version of the IFU together with the PER.
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- the completed metadata template ¹⁵ which includes the completed template from MDCG 2021-22;
- the PER of the manufacturer (it is encouraged to also including the most updated version of the instruction for use).

The metadata template also includes a document checklist. It has to be completed for each PECP dossier and transmitted for IVD panel consultation.

4.3.2. Marking of all the documents according to the Commission marking instructions

The documents to be transmitted for expert consultations are likely to contain commercially confidential information and trade secrets. Within the Commission, such information is considered “sensitive non-classified” (SNC) and there are specific rules for the handling of such information by Commission and external experts, in particular to avoid that such information is accidentally divulged beyond Commission staff and experts. Notably, all experts are required to sign a declaration of confidentiality which obliges them not to divulge any information that they have acquired in the course of their work as appointed experts.

In order to ensure awareness of the need to treat such documents with the necessary precautions, SNC information needs to be marked in agreement with the Commission Security Notice 1904 on “*marking and handling of sensitive non-classified information*”. To this end security and distribution markings need to be inserted in the title part of individual electronic documents by the document proprietors. NBs have the responsibility of ensuring that the MF’s documents have been appropriately marked. To facilitate the work of NBs, specific marking instructions are outlined in a separate document¹⁶.

Briefly, NBs need to ensure that the documents have the relevant markings on the front page (i.e., only one marking per document):

- the security marking SENSITIVE and
- the distribution marking RELEASABLE TO: EXPERT PANELS (EXPAMED).

This should be done before transferring the dossier to the secretariat via CIRCABC. The expert panel Secretariat will check the accuracy of the markings. In case these are inaccurate, the NB will be requested to amend these.

4.3.3. Upload of documents on the NB space on secure CIRCABC

Once the documents have been appropriately marked, the NB needs to submit these in the secure system made available for the purpose.

The CIRCABC interest group must only be used for submissions of CECP or PECP consultation requests. It is located under the following link:

<https://classified.circabc.europa.eu/ui/group/313a8bbb-b442-4c04-a4d6-eb7bc78e323f>

To facilitate the work of NBs, specific instructions for transmitting documents in relation to a CECP dossier are outlined in a separate document¹⁷.

¹⁵ **Expamed document D5.3:** Template for notified bodies: submission metadata and document checklist

¹⁶ **Expamed document D5.2:** How to mark the documents to be transmitted to the Secretariat of the European Commission Expert Panels on medical devices and in vitro diagnostic medical devices (Expamed)

¹⁷ **Expamed document D5.4:** Instructions for transmitting documents in relation to a CECP or PECP dossier

4.4. PECP step 4: Consultation of the IVD panel

Following the upload of a new consultation dossier by a NB, the Secretariat will coordinate the consultation with the experts.

4.4.1. Responsibilities of the Secretariat prior to transmitting the dossier to the experts

While the Secretariat will make all reasonable efforts to transmit the dossier to the experts as soon as possible, it should be noted that there are various steps that need to be completed beforehand. These include but are not restricted to:

- **checking the completeness of the dossier** in order to ensure that the experts will receive all the necessary information for their assessment;
- **analysis of potential conflicts of interests (COI)** of experts in relation to a specific dossier and assignment of experts without COI to a specific dossier. This implies that the latest DOI is furnished and is complete;
- **communications with experts** determining their availability to work on a dossier and providing support throughout the procedure.

4.4.2. Coordination of the consultations by the Secretariat

The Secretariat will forward the dossier to the IVD panel. Views of the IVD panel have to be finalised within the 60 days' timeframe of the PECP consultation according to IVDR Article 48(6). NBs will be informed by email about the timepoint when the panel experts have received the dossier. They will be informed about the result of the panel consultation via upload of the views of the IVD expert panel once concluded by the experts.

4.5. PECP step 5: consideration of the expert panel view in the conformity assessment by the NB

If views of the IVD expert panel are received within the 60 calendar day timeline, the NB is obliged to give due consideration to the experts' advice when finalising both the PEAR report and the conformity assessment report. In particular, and if applicable, NB is expected to update its PEAR taking into account comments of the expert panel in the final version. The final version of the PEAR is to be used for notification under IVDR Article 50.

The expert panel views will be published on the website for expert panels.

5. Publication of CECP opinions and PECP views

The Agency is obliged to publish the opinions, views and advice delivered by expert panels in accordance with Article 106(9) and 106(11) of the MDR and Article 30 (d) of the extended mandate, ensuring consideration of aspects of confidentiality as set out in Article 109(1). Article 109(1) outlines that commercially confidential information and trade secrets should not be disclosed unless in the public interest. Commercially confidential information is defined as any information which is not in the

public domain or publicly available, and where disclosure may undermine the economic interest or competitive position of the owner of the information¹⁸.

According to Article 14 of the Commission Implementing Decision (EU) 2019/1396 on the designation of expert panels in the field of medical devices, the Secretariat shall make opinions or views available to the public on a dedicated website and without undue delay, after handling the confidentiality and transparency aspects.

The NB informs the secretariat once the certification procedure is completed, either with the issuing of a certificate, its refusal¹⁹ or the manufacturer's withdrawal of its application. The Secretariat sends to the NB a table to be completed by the NB to identify any elements of the opinion/view that are deemed to be commercially confidential information, trade secrets or related to personal data protection. Each identified case needs to be duly justified in the table. The NB needs to respond within fourteen calendar days, from receiving the above-mentioned table. Potential confidential information is expected to be already identified during the certification process and reassessed when submitting the table to the Secretariat based on currently available information in the public domain.

Taking the feedback provided in the table into consideration, the Secretariat assesses on a case-by-case basis each request for redaction, prepares the final version of the expert panel's opinion/view for publication, and sends this version to the NB along with the replies to the NB's requests for redaction.

Opinions and views will be published on a dedicated website.

¹⁸ According to "HMA/EMA GUIDANCE DOCUMENT ON THE IDENTIFICATION OF COMMERCIALY CONFIDENTIAL INFORMATION AND PERSONAL DATA WITHIN THE STRUCTURE OF THE MARKETING AUTHORISATION (MA) APPLICATION - RELEASE OF INFORMATION AFTER THE GRANTING OF A MARKETING AUTHORISATION"

¹⁹ According to Article 56(5) MDR, the NB shall make publicly available in Eudamed "any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates". In the absence of the corresponding functionality of Eudamed, this information is not available and the notified body is asked to share it with the Secretariat in view of the timely publication of the opinions of the expert panels.

Abbreviations

CAR	Conformity Assessment Report
CEAR	Clinical Evaluation Assessment Report
CECP	Clinical Evaluation Consultation Procedure
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
COI	Conflict of Interests
COM	European Commission
DOI	Declaration of Interests
ECAS	European Commission Authentication Service
EUDAMED	European Database for Medical Devices
EXPAMED	Expert panels on medical devices and in vitro diagnostic medical devices
IFU	Instructions for Use
IVD	<i>In vitro</i> diagnostic medical devices
IVDR	Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices
MDCG	Medical Devices Coordination Group
MDR	Regulation (EU) 2017/745 on medical devices
MF	Manufacturer
MS	Member State(s)
NB	Notified Body
PECP	Performance Evaluation Consultation Procedure
PER	Performance Evaluation Report
PEAR	Performance Evaluation Assessment Report
PMCF	Post Market Clinical Follow-up
SNC	Sensitive Non-Classified
SSCP	Summary of safety and clinical performance
SSP	Summary of safety and performance

Annex I: Outline of documents to be forwarded for CECP

The clinical evaluation assessment report (CEAR)

The MDR (Annex IX, Section 5.1 (a)) outlines specific requirements in regard to the CEAR:

*"For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12), the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare a clinical evaluation assessment report which sets out its **conclusions concerning the clinical evidence provided by the manufacturer**, in particular concerning the **benefit-risk determination**, the **consistency of that evidence with the intended purpose**, including the **medical indication or indications** and the **PMCF plan** referred to in Article 10(3) and Part B of Annex XIV."*

The MDCG 2020-13 *Clinical evaluation assessment report template*²⁰ makes available a harmonised template that provides a standardised method for documenting the NB's assessment of the manufacturer's clinical evaluation and related documents. The CEAR template also includes a specific section (section I) on devices qualifying for the CECP procedure that outlines the points below which are of particular relevance for the expert panel consultation:

- novel aspects of the device or of the relevant clinical procedure and possible major clinical/health impact;
- the adequacy of the benefit-risk determination provided by the MF;
- the consistency of clinical evidence with purpose of the device under assessment;
- the PMCF plan.

This section further allows the NB to suggest what would be the relevant medical field for the device under examination and the associated competences required.

In order to be submitted to the Secretariat, the CEAR needs to be finalised with all applicable sections completed and the conclusion of the NB has to be positive, highlighting the aspects that led the NB to consider that the manufacturer has provided sufficient and adequate clinical evidence to demonstrate conformity with the general safety and performance requirements in view of the characteristics of the device and its intended purpose.

Before submitting the CEAR, all applicable sections should be completed, relevant conclusions reached, and corresponding boxes ticked for the report to be considered complete. The personal data within the CEAR will be treated as per NB's procedures for the management of personal data in compliance with Regulation (EU) 2016/679 General Data Protection Regulation.

The clinical evaluation report (CER)

Along with the CEAR, the CER of the MF will also be submitted. The mention regarding the updates of the CER made in point 6.1 (c) of Annex II *Technical documentation*, is not relevant for the CECP, as there are no updates of the CER to be submitted for the devices undergoing their first certification under the MDR.

²⁰ https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-13-cea-report-template_en.pdf

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The clinical evaluation plan (CEP)

The clinical evaluation plan drawn up in accordance with point 1 (a) of Annex XIV *Clinical evaluation and post-market clinical follow-up*, will also be part of the submission file.

The post market clinical follow-up plan (PMCF plan)

The PMCF plan will be drawn up in accordance with points 6.1, 6.2 of Annex XIV *Clinical evaluation and post-market clinical follow-up*. The MDCG 2020-7 *Post-market clinical follow-up (PMCF) Plan Template*²¹ offers guidance and a template covering the elements of this document. If the PMCF is not applicable, a justification to this end will be submitted.

The post-market clinical follow-up evaluation report (PMCF Evaluation Report)

The PMCF Evaluation Report will be drawn up in accordance with point 7 of Annex XIV *Clinical evaluation and post-market clinical follow-up*. MDCG 2020-8 *Post-market clinical follow-up (PMCF) Evaluation Report Template*²² offers guidance and a template covering the elements of this document. If the PMCF is not applicable, a justification to this end will be submitted.

Notably, at the time of expert consultation, the PMCF evaluation report relating to the pending certification procedure under the MDR will not be available – irrespective of whether or not the device has been marketed before under the MDR or the Directives (see **Figure 6**). However, for modifications of MDR-certified devices and for modifications of devices already marketed before under the Directives ('legacy devices'), previous information from PMS or PMCF may have been used as clinical data for clinical evaluation in the context of the current certification procedure (see **Figure 6, A2 and A3**). In such cases, the relevant documents/reports corresponding to previous generations of the device should be included in the CECP dossier. For modifications of previously MDR certified devices, the PMCF report should follow the MDCG template 2020-8, while the PMCF report for legacy devices covering the period of certification under the relevant Directives, does not need to be re-formatted to follow this template. What is important is that the evidence is available to the expert panels and reformatting will not change the level and extent of evidence available.

²¹ <https://ec.europa.eu/docsroom/documents/40905>

²² <https://ec.europa.eu/docsroom/documents/40906>

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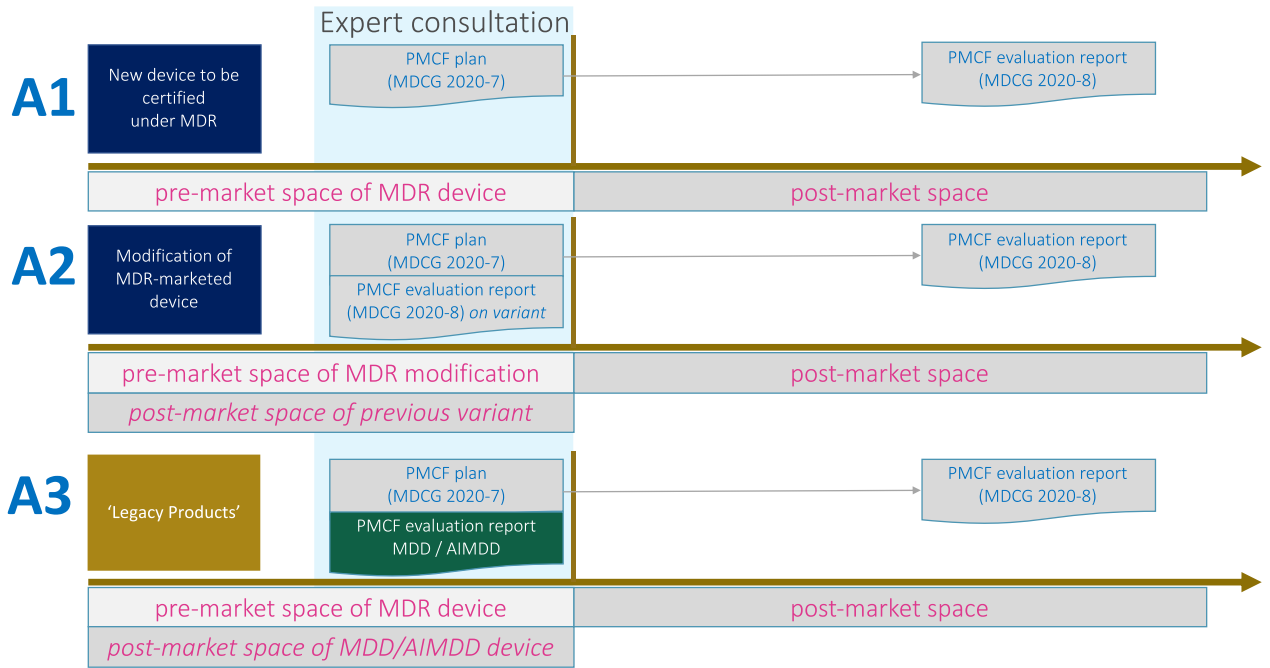


Figure 6: PMCF reports for new devices to be certified under MDR (A1), for modification of MDR-marketed devices that may enter CECP (A2) and for legacy devices (A3)

Annex II: CIRCABC platform

The CIRCABC platform (Communication and Information Resource Centre for Administrations, Businesses and Citizens) is owned by European Commission. **NBs are enabled to use the secure version of CIRCABC.** Secure CIRCABC is used during the CECP and PECP to exchange documents between the actors of the procedure (NB, Secretariat and expert panels). Files are stored under the section "Library" and are organised in appropriate folders and sub-folders.

Each NB designated for devices that qualify for CECP has its own dedicated secure space on CIRCABC. This dedicated space is only accessible to the relevant NB personnel (having been given access rights by the Secretariat) as well as the Secretariat. Experts do **not** have access to the NB folders. **Figure 3** shows the organisation and configuration of secure CIRCABC for document exchange in the context of the CECP.

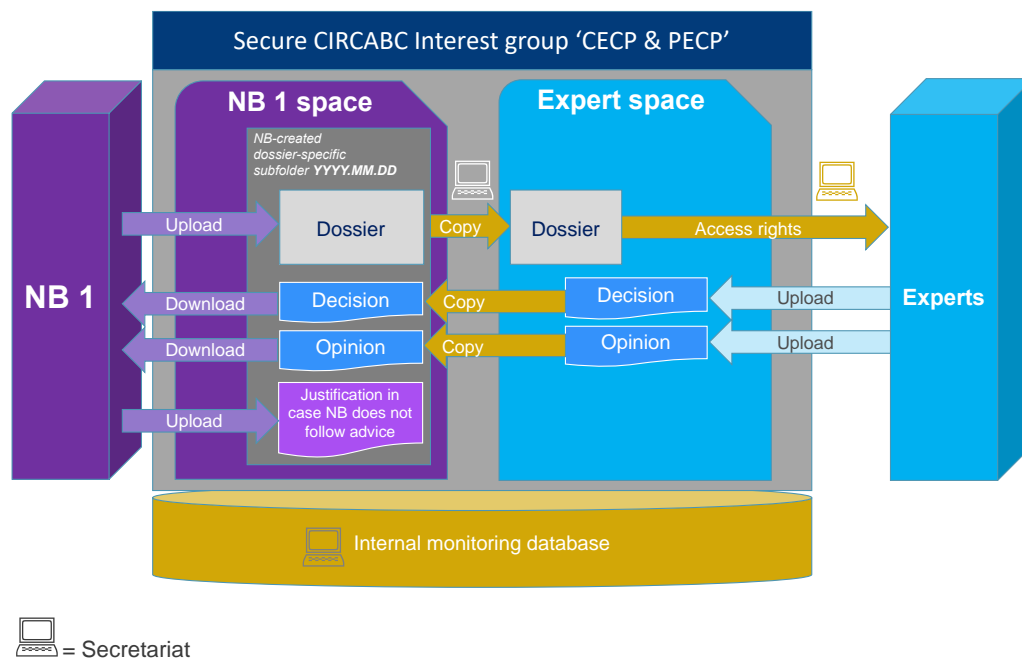


Figure 3: Organisation and configuration of secure CIRCABC for document exchange in the context of the CECP

CIRCABC sends e-mail **notifications** to authorized users whenever the content of their respective folder(s) is modified (e.g., new file uploaded, downloaded). This notification function will be used for alerting NBs to the upload of:

- **decisions** by screening experts when there is no intention to provide an opinion;
- **opinions or views** of expert panels.
- The notification function will also alert the Secretariat to the upload of:
- **a specific CECP dossier by a NB;**
- **a justification by a NB** in case the NB has not followed the expert panel advice provided in the context of the CECP.

For the time being, the secure CIRCABC notifications replace those foreseen in the MDR to be managed via EUDAMED (see Commission Guidance²³).

²³ https://ec.europa.eu/health/system/files/2021-05/2021-1_guidance-administrative-practices_en_0.pdf
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Annex III: Registration and upload / download of documents in CIRCABC

NB's dedicated space on CIRCABC

Each NB designated for devices that qualify for CECP and PECP has its own dedicated secure space on CIRCABC. This dedicated space is only accessible to the relevant NB personnel (having been given access rights by the Secretariat) and the Secretariat. New users can only be added by the Secretariat, a request for a new user can be sent via E-Mail to the secretariat from an already existing user. Expert panels will not have access to the NB folders. In case of a newly designated NB, the names of the users should be communicated via E-Mail to the secretariat.

After the login procedure, the relevant NB personnel has access only to one folder as shown in Figure 1. In that folder the relevant NB personnel can create subfolders and upload/download files.

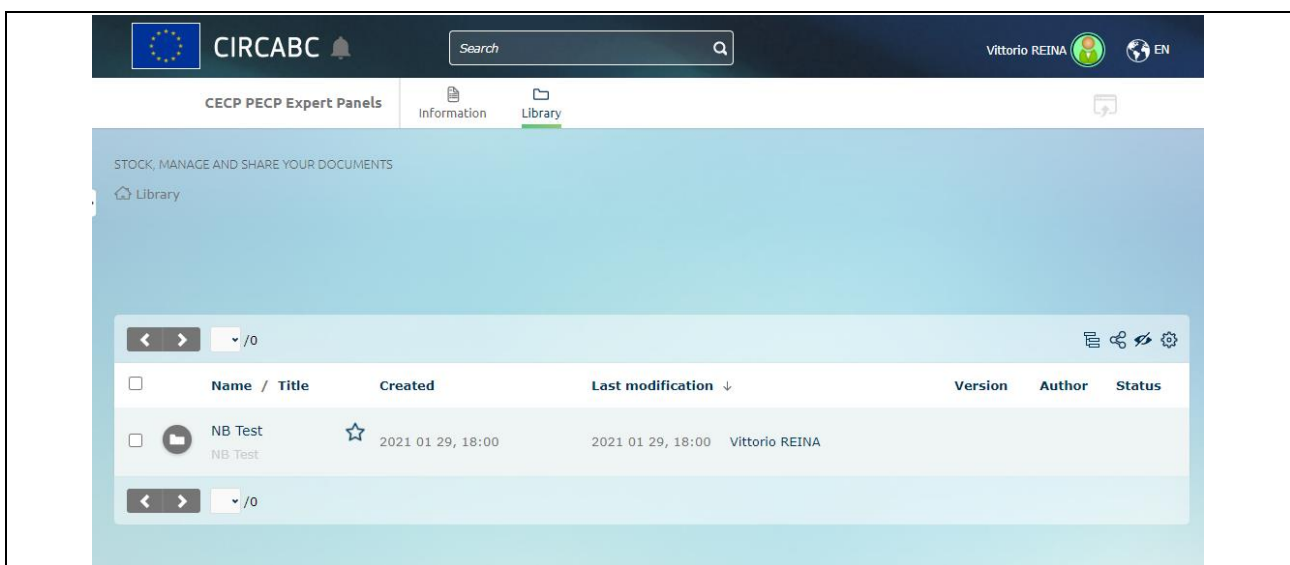


Figure 1: View of the Library after login

EU Login account

The EU Login account, managed by the European Commission's user authentication service (abbreviated as ECAS), allows authorised users to access Commission web services, using a single email address and password.

CIRCABC uses EU Login as authentication service. To access content stored in CIRCABC, users need an EU Login account.

The secure CIRCABC requires EU Login with one of the following complementary 2-factors authentication methods:

- Mobile Phone + SMS (which is the preferred option)
- EU Login Mobile App PIN Code

If you already have an EU Login account you can skip next point a) and if already associated a mobile phone number to your EU Login account you can skip point b).

a) Creating an EU Login account

To create an EU Login, use the link <https://webgate.ec.europa.eu/cas/about.html> and click **Create an account** as shown in Figure 2.

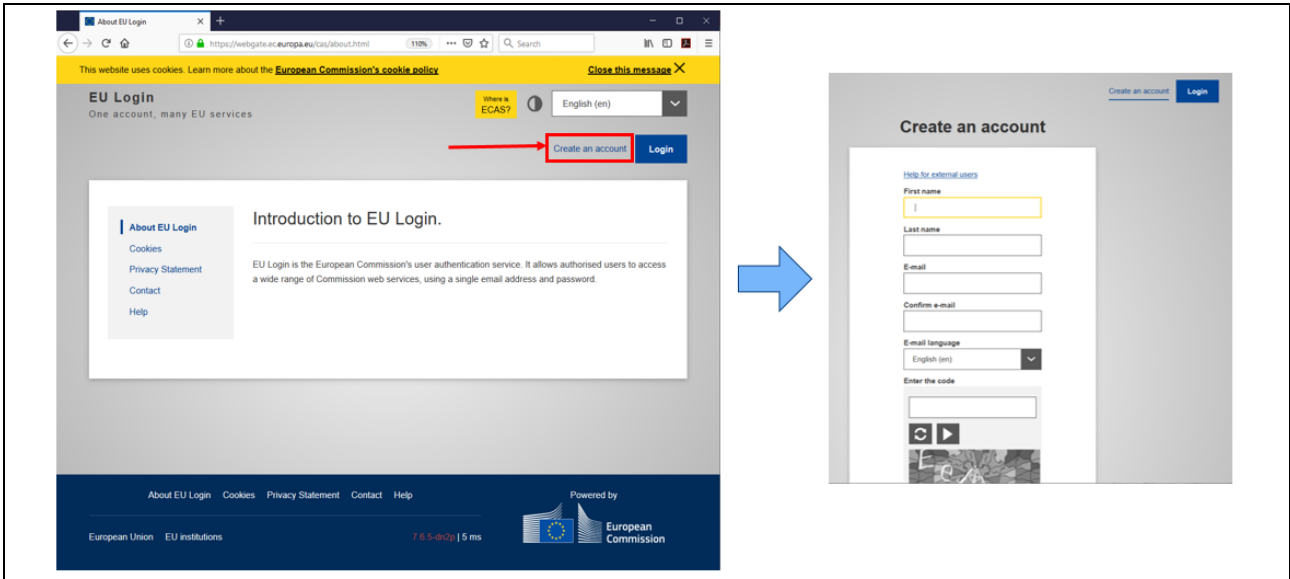


Figure 2: Creating an EU Login

b) Adding a mobile phone number to an EU Login account

When the EU Login is created, to access the secure CIRCABC, it is necessary to associate to it a mobile phone number. The mobile phone number is requested by the 2-factors authentication procedure to access the CECP PECP Expert Panels Interest Group. To do that:

1. Login at <https://webgate.ec.europa.eu/cas/about.html>;
2. Click the gear icon beside your name to access "My Account" page where you can configure your account (e.g., your personal data) as shown in Figure 3.

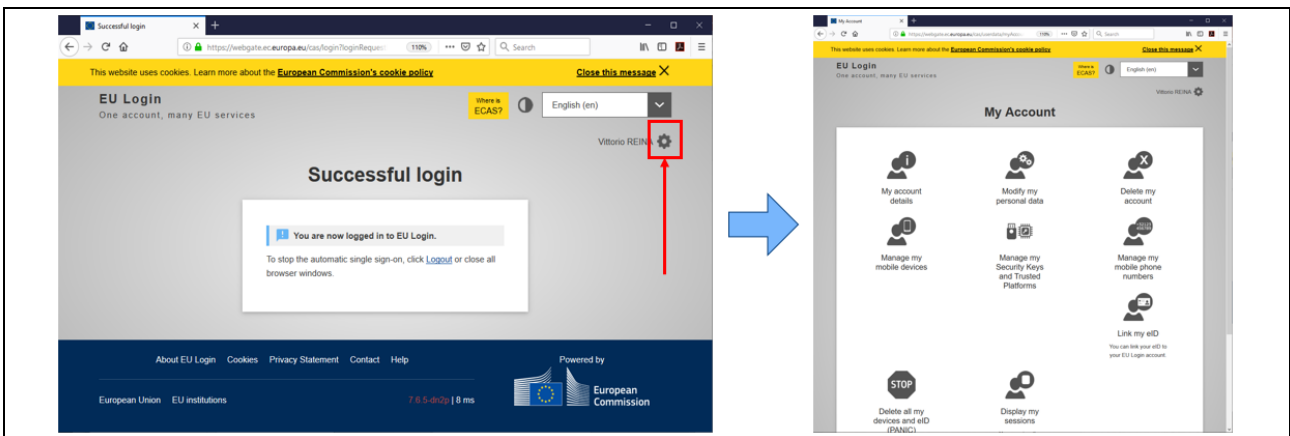


Figure 3: My Account page

When you are in the "My Account" page:

1. Click **Manage my mobile phone numbers**, insert your password and mobile phone number and click **Sign in**

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2. You will receive an SMS with a code. Usually this code will arrive on your mobile phone within 1 to 2 minutes only rarely it requires more time.
3. Insert the code in the required fields
4. Click **Sign in** to finalise the operation

The procedure is illustrated in Figure 4.

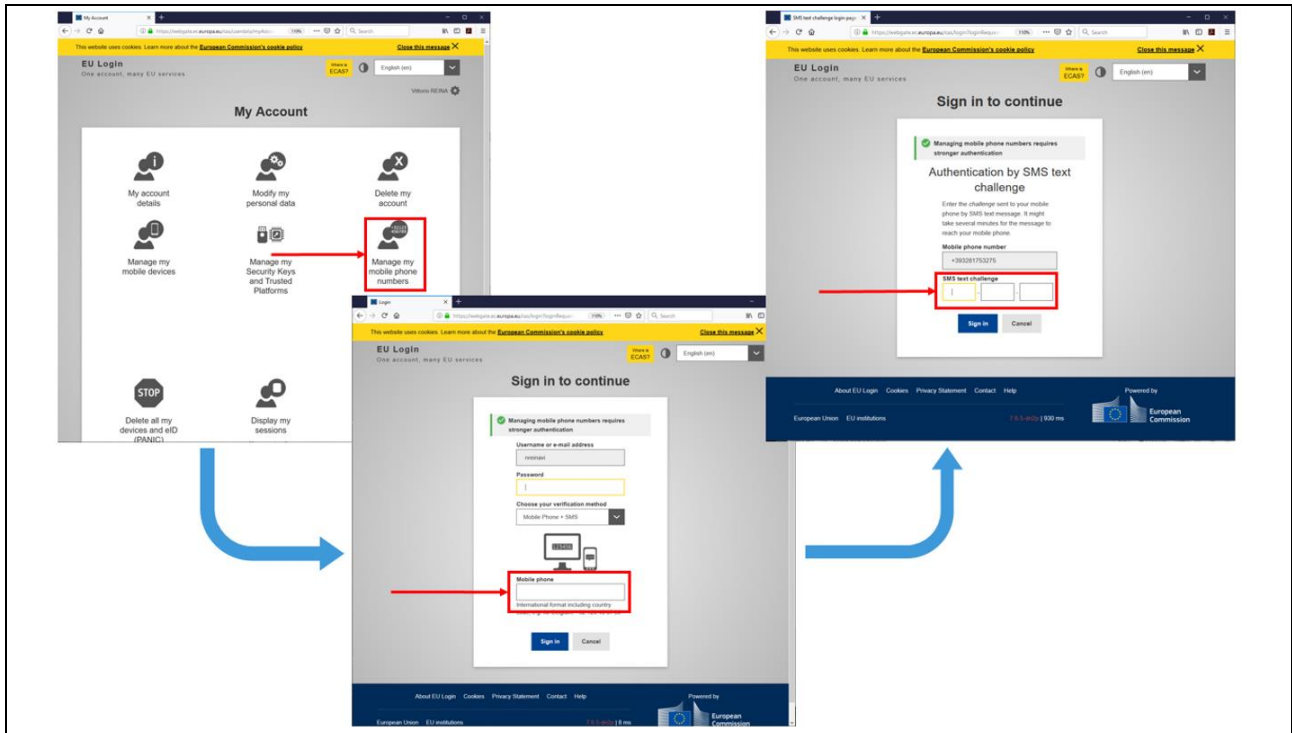


Figure 4: Adding a mobile phone number to an EU Login account

Accessing the CECP PECP Expert Panels Interest Group

The CECP PECP Expert Panels Interest Group is accessible at:

<https://classified.circabc.europa.eu/ui/group/313a8bbb-b442-4c04-a4d6-eb7bc78e323f>

In the login window:

1. Type your **password**, select **Mobile Phone + SMS**, insert the **mobile phone** associated with your account and click **Sign in**.
2. You will receive an SMS with a code. Usually this code will arrive on your mobile phone within 1 to 2 minutes only rarely it requires more time.
3. Insert the code in the required fields.
4. Click **Sign in** to finalise the operation and access the homepage

The procedure is illustrated in Figure 5.

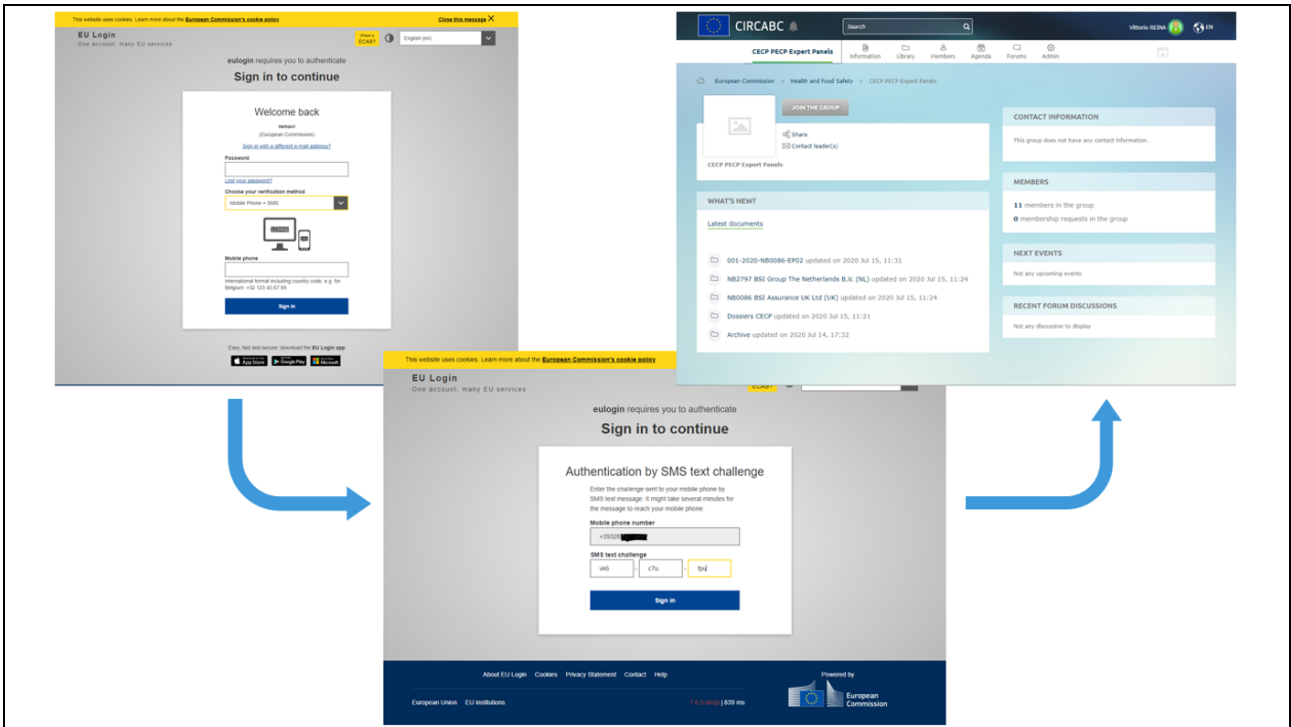


Figure 5: Login to the CECP PECP Expert Panels Interest Group

Managing files in CIRCABC

Files in CIRCABC are stored under the section **Library** and are organised in folders and sub-folders. You see only folders for which you have access rights. An example is shown in Figure 6.

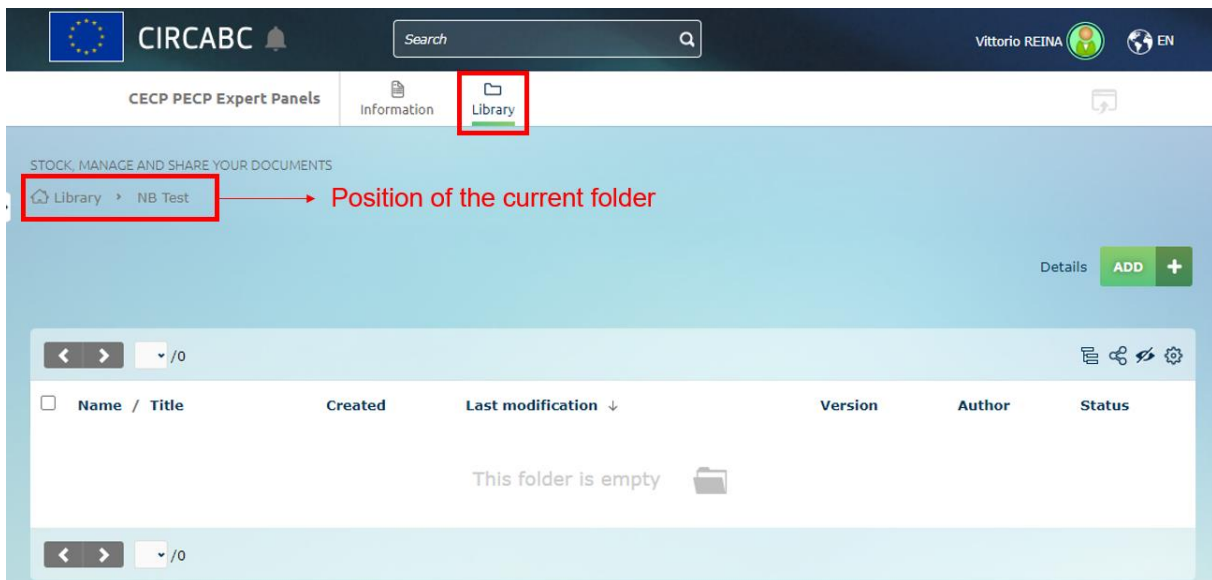


Figure 6: Content of a folder in the CECP PECP Expert Panels Interest Group

a) Creating sub-folders

For each CECP, in order to submit the necessary files (e.g., CEAR), you have to create a subfolder in your dedicated folder by following the next steps as shown in Figure 7:

1. Click on **ADD**, which opens a small window from where you can select **FOLDER**.

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2. Type the Name of the new sub-folder using the following format: current date (YYYY.MM.DD). In case more than one dossier is transmitted at a given day, use an additional letter code in agreement with the following format:

YYYY.MM.DD-(A), YYYY.MM.DD-(B) etc.; The NB is free to add additional information as their own reference.

3. Click **CREATE**

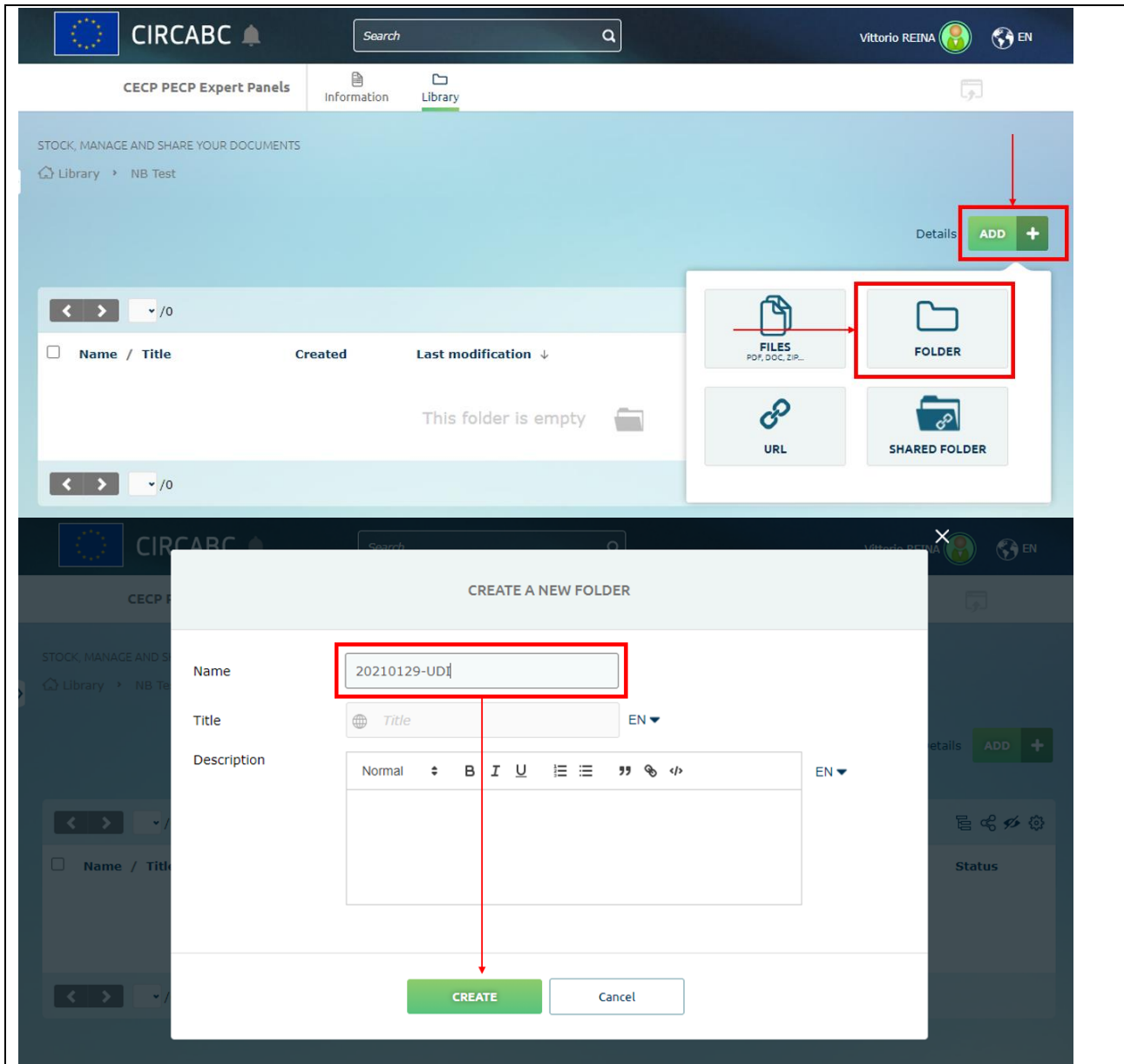


Figure 7: Creating a sub-folder

b) Uploading files

To upload the CEAR and the relevant MF's documents (e.g., CEP, CER, PMFC) for a CECP, go the dossier sub-folder that you have created in your dedicated folder (see 4.b) and then follow the next steps as shown in Figure 8:

1. Click on **ADD**, which opens a small window from where you can select **FILES**.

2. Click **ADD FILES** and following the file path on your PC where you have them stored. Alternatively, you can simply drag and drop the file(s) in the dashed area
3. The marking "Sensitive" should be selected and it should be ensured that the user rights are inherited from the folder.
4. Click **UPLOAD** and then **FINISH**. Upload limit is 300Mb per file.

When correctly configured, this action will trigger a notification (see section 5) to the Secretariat of the panels.

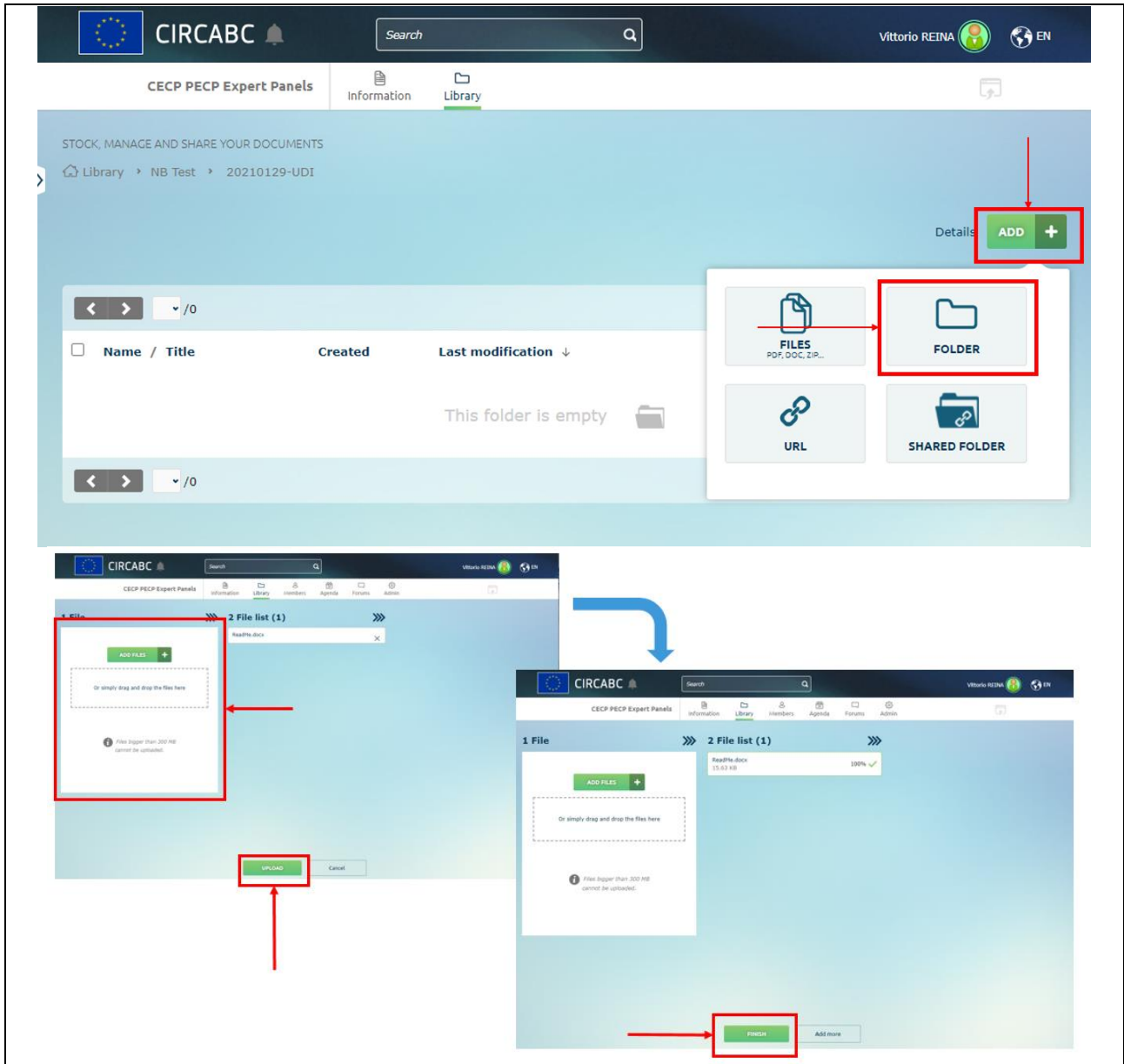


Figure 8: Uploading files

c) Downloading files

If you need to download one file, go from the Library to your dedicate folder and follow the next steps illustrated in Figure 9:

1. Place the mouse on the name of the file. A submenu will appear with several actions (according to your access rights)

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2. Click **Download**

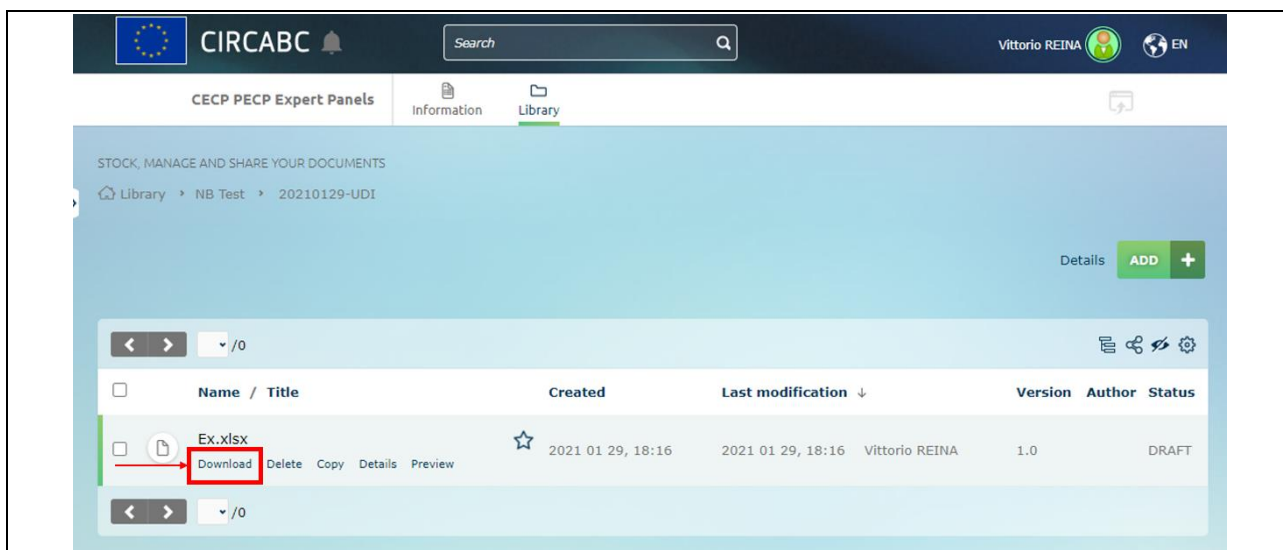


Figure 9: Downloading one file

If you need to download multiple files, follow the next steps illustrated in Figure 10:

1. Select the files using the checkbox on the left of the filenames.
2. Click **Download**

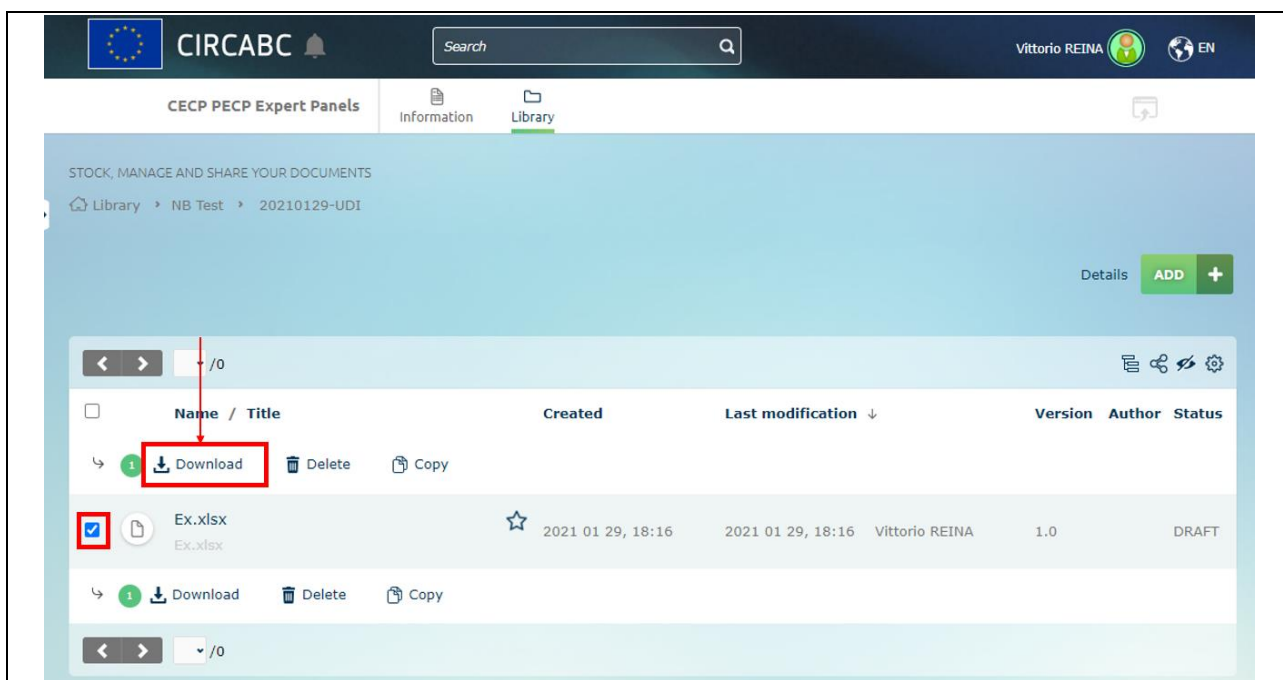


Figure 10: Downloading multiple files

Notifications

CIRCABC has the capability, if enabled, to send email notifications to users having access to a folder when the content of that folder is modified (e.g., new file uploaded). **You will receive such notifications when the decision by the screening experts and the scientific opinion of medical devices expert panel are copied in your dedicated folder.**

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Notification email look like the one shown in Figure 11. In order to directly access the modified content without browsing the Library to find it, you have two alternatives:

1. To access the modified folder click the button **Visit** coloured in green.
2. To access the file(s) click the "Direct access URL" or the button **Visit** not coloured.

Please note that if you are not signed in, you will have to follow the 2-factors authentication login procedure presented in section 3 after clicking **Visit**.

