

Annex II

Instructions for submitting the application

1. Member States are requested to submit the applications not later than 12:00 Central European Time on **31 March 2023**. **No extension of the deadline is possible and any applications submitted after this deadline will not be considered.**

It is highly recommended that candidate laboratories send their applications to their Member States no later than 12:00 (midday) Central European Time on 05 January 2023.

2. Member States must carefully follow the instructions in this call.
3. Only applications submitted by the Member States or the European Commission's Joint Research Centre (JRC) and for which they have verified the compliance with selection criteria will be considered.
4. Member States or the JRC must complete and submit the following documents:
 - Application form (Annex III or Annex IV)
 - Visa section Declaration on honour regarding exclusion criteria (Annex V)
 - Visa section of Declaration of independence of the candidate laboratory (Annex VII)
 - Template for verification of compliance with selection criteria (Annex XI)
 - Confirmation of the Member States regarding the performance of tasks in the public interest and in an independent manner (Annex XII)

In addition, Member States are responsible for submitting the supporting documents referred to in sections 3 and 4 of this call, as prepared by the candidate laboratories. Supporting documents for the selection criteria in section 3 are requested at the initial application stage, by the above deadline. Supporting documents for the preference criteria in section 4 might be requested by the European Commission at a later stage and only in case of need.

5. The application must be submitted electronically via Secure CIRCABC. Each Member State will have its own dedicated folder in the relevant Secure CIRCABC Interest Group. Individual Member State representatives will need to have a personal EU Login account¹ that will be granted for accessing this folder. To nominate up to 3 Member States representatives for access to the CIRCABC Interest group, please send an email to: JRC-MEDICAL-DEVICES@ec.europa.eu with their name/surname and email addresses. Accessing Secure CIRCABC requires EU Login with 2-factors authentication methods (e.g. Mobile Phone + SMS)². Then proceed with the following steps:
 - Access the Secure CIRCABC Interest Group at <https://classified.circabc.europa.eu/>

¹ EU Login accounts can be created at <https://webgate.ec.europa.eu/cas/about.html>

² To add a mobile phone number to a EU Login account, login to <https://webgate.ec.europa.eu/cas/about.html> Click to gear icon beside the user name (at the top right of the page). Click *My Account* page and then *Manage my mobile phone numbers*

- On the top Menu click *Library*, then click the folder of the Member State
- Click the Button *ADD* and select *FILES*
- Select the file(s) to be uploaded by clicking *ADD FILES* or simply dragging and dropping the file(s) in the dashed area
- Click *UPLOAD* and then *FINISH*

Applications submitted by other means will not be considered. For technical assistance during the submission, please send an email to: JRC-MEDICAL-DEVICES@ec.europa.eu