**Annex X**

**Template for verification of compliance with the selection criteria by the Member State**

Nominating Member State: ………………………………………………..

Competent authority: ………………………………………………………….

Single laboratory application

Consortium application – Please fill a separate verification template for each member of the consortium

Full name of candidate laboratory in English: ………………………………………..

Full name of candidate laboratory in national language:……………………………………

The candidate laboratory is accredited in accordance with EN ISO/IEC 17025:

No – Please fill Table 1 starting on page 2.

Yes – Issuing entity, date and number of certificate: ………………………………………….

In accordance with the above accreditation and Article 8 of the Commission Implementing Regulation 2022/944, the nominating Member State may grant presumption of conformity to the candidate laboratory for certain requirements set out in the Regulation 2022/944.

Presumption of conformity is granted:

Yes – Please fill Table 2 and 3 starting on page 7.

No – Please fill Table 1 starting on page 2.

Table 1: Verification table for candidate laboratories without ISO 17025 accreditation in scope of the EURL application

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| --- | --- | --- | --- | --- |
| **Criterion No** | **Means of proof** | **Supporting documents provided.**  Please tick if yes and specify the document name | **Member State verification.**  **Are the documents compliant with the selection criteria?** | **Justification / Comments - if any** |
| 1.1 | List of knowledge and experience requirements for the director, the scientific staff and the technical staff | document(s) name: | yes no |  |
| 2.1 | Overview tables for knowledge and experience of the staff and the supporting documents | document(s) name: | yes no |  |
| 3.1 | Estimate of minimum capacity regarding performance verification | document(s) name: | yes no |  |
| 3.2 | Estimate of minimum capacity regarding batch testing | document(s) name: | yes no |  |
| 3.3 | Justification regarding the number of staff | document(s) name: | yes no |  |
| 4.1 | Description of the continuous training and education programme for the staff | document(s) name: | yes no |  |
| 5.1 | Justification regarding equipment and reference materials | document(s) name: | yes no |  |
| 5.2 | Evidence of possession of equipment and reference materials | document(s) name: | yes no |  |
| 5.3 | Plan for procurement of specimens, control materials and reference materials | document(s) name: | yes no |  |
| 6.1 | List of international standards and best practices, including common specifications | document(s) name: | yes no |  |
| 6.2 | Evidence of integration international standards and best practices, including common specifications | document(s) name: | yes no |  |
| 7.1 | Identification of the person having overall responsibility | document(s) name: | yes no |  |
| 8.1 | Estimate regarding volume of administrative work | document(s) name: | yes no |  |
| 8.2 | Justification of the number of administrative staff | document(s) name: | yes no |  |
| 9.1 | Evidence of the laboratory’s status as a legal entity | document(s) name: | yes no |  |
| 9.2 | If the laboratory is part of a larger organisation, information related to that larger organisation | If applicable:  document(s) name: | yes no |  |
| 9.3 | If the laboratory is, directly or indirectly, controlled by other entities, the identity of such entities and their controlling position | If applicable:  document(s) name: | yes no |  |
| 9.4 | Description of the laboratory’s internal organisational structure | document(s) name: | yes no |  |
| 9.5 | Description of the operating procedures | document(s) name: | yes no |  |
| 9.6 | Evidence of sources of funding | document(s) name: | yes no |  |
| 9.7 | Declaration on honour regarding exclusion criteria | Candidate declaration  Member State visa  document(s) name: | yes no |  |
| 9.8.1 | Economic viability template | document(s) name: | yes no |  |
| 9.8.2 | Balance sheets, profit and loss accounts or annual reports for the last three financial years | document(s) name: | yes no |  |
| 9.8.3 | Audit reports from the last three financial years | Where available:  document(s) name: | yes no |  |
| 9.9 | Proposed system for records of costs and fees | document(s) name: | yes no |  |
| 10.1 | Confidentiality policy including the following: | document(s) name: | yes no |  |
| 10.1.1 the type of information that is considered confidential | document(s) name: | yes no |  |
| 10.1.2 rules for the appropriate secure handling, storage and processing of confidential information and measures to prevent undue disclosure | document(s) name: | yes no |  |
| 10.1.3 rules for sharing of confidential and non-confidential information with staff, and the public | document(s) name: | yes no |  |
| 10.1.4 rules for granting access to confidential information to a competent authority of a Member State upon its request in the context of market surveillance or vigilance activities by the competent authority | document(s) name: | yes no |  |
| 10.1.5 rules for sharing confidential information, on the initiative of the EU reference laboratory, with a competent authority of a Member State and with the European Commission where the EU reference laboratory has reason to believe that such sharing is in the interest of protection of public health | document(s) name: | yes no |  |
| 10.2 | List of measures to ensure that the staff complies with the confidentiality policy | document(s) name: | yes no |  |
| 11.1 | Confirmation by the Member States regarding the performance of tasks in the public interest and in an independent manner | document(s) name: | yes no |  |
| 12.1 | Policy for the management of conflict of interest | document(s) name: | yes no |  |
| 13.1 | Declaration of independence of the candidate laboratory | Candidate declaration  Member State visa  document(s) name: | yes no |  |
| 14.1 | List of requirements regarding the tasks covered by the contract | If applicable:  document(s) name: | yes no |  |
| 14.2 | Declaration regarding the external laboratories | If applicable:  document(s) name: | yes no |  |

Table 2: Verification table 1 for candidate laboratories with ISO 17025 accreditation in the scope of the EURL application

|  |  |  |
| --- | --- | --- |
| **Criterion No** |  | **Member State granted presumption of conformity for the following Articles of Regulation (EU) 2022/944 to the EN ISO/IEC 17025 accredited candidate laboratory** |
| 1.1 | List of knowledge and experience requirements for the director, the scientific staff and the technical staff | Article 1(1) |
| 2.1 | Overview tables for knowledge and experience of the staff and the supporting documents | Article 1(2) |
| 3.3 | Justification regarding the number of staff | Article 1(3) |
| 4.1 | Description of the continuous training and education programme for the staff | Article 1(4) |
| 5.2 | Evidence of possession of equipment and reference materials | Article 2(1), point (b) |
| 7.1 | Identification of the person having overall responsibility | Article 4(1) |
| 8.1 | Estimate regarding volume of administrative work | Article 4(2) |
| 8.2 | Justification of the number of administrative staff | Article 4(2) |
| 9.1 | Evidence of the laboratory’s status as a legal entity | Article 4(3), point (a) |
| 9.4 | Description of the laboratory’s internal organisational structure | Article 4(3), point (d) |
| 9.5 | Description of the operating procedures | Article 4(3), point (e) |
| 10.1 | Confidentiality policy including the following: |  |
| 10.1.1 the type of information that is considered confidential | Article 5(1), point (a) |
| 10.1.2 rules for the appropriate secure handling, storage and processing of confidential information and measures to prevent undue disclosure | Article 5(1), point (b) |
| 10.1.3 rules for sharing of confidential and non-confidential information with staff, and the public | Article 5(1), point (c) |
| 10.2 | List of measures to ensure that the staff complies with the confidentiality policy | Article 5(2) |
| 12.1 | Policy for the management of conflict of interest | Article 6(2) |
| 14.2 | Declaration regarding the external laboratories | Article 7(3), point (a), (b), (c) |

|  |  |
| --- | --- |
| Certificate of accreditation according to EN ISO/IEC 17025 | Certificate provided |

Table 3 Verification table 2 for candidate laboratories with ISO 17025 accreditation in the scope of the EURL application

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| --- | --- | --- | --- | --- |
| **Criterion No** | **Means of proof** | **Supporting documents provided.**  Please tick if yes and specify the document name | **Member State verification.**  **Are the documents compliant with the selection criteria?** | **Justification / Comments - if any** |
| 3.1 | Estimate of minimum capacity regarding performance verification | document(s) name: | yes no |  |
| 3.2 | Estimate of minimum capacity regarding batch testing | document(s) name: | yes no |  |
| 5.1 | Justification regarding equipment and reference materials | document(s) name: | yes no |  |
| 5.3 | Plan for procurement of specimens, control materials and reference materials | document(s) name: | yes no |  |
| 6.1 | List of international standards and best practices, including common specifications | document(s) name: | yes no |  |
| 6.2 | Evidence of integration international standards and best practices, including common specifications | document(s) name: | yes no |  |
| 9.2 | If the laboratory is part of a larger organisation, information related to that larger organisation | If applicable:  document(s) name: | yes no |  |
| 9.3 | If the laboratory is, directly or indirectly, controlled by other entities, the identity of such entities and their controlling position | If applicable:  document(s) name: | yes no |  |
| 9.6 | Evidence of sources of funding | document(s) name: | yes no |  |
| 9.7 | Declaration on honour regarding exclusion criteria | Candidate declaration  Member State visa  document(s) name: | yes no |  |
| 9.8.1 | Economic viability template | document(s) name: | yes no |  |
| 9.8.2 | Balance sheets, profit and loss accounts or annual reports for the last three financial years | document(s) name: | yes no |  |
| 9.8.3 | Audits reports from the last three financial years | Where available:  document(s) name: | yes no |  |
| 9.9 | Proposed system for records of costs and fees | document(s) name: | yes no |  |
| 10.1 | Confidentiality policy including the following: |  |  |  |
| 10.1.4 rules for granting access to confidential information to a competent authority of a Member State upon its request in the context of market surveillance or vigilance activities by the competent authority | document(s) name: | yes no |  |
| 10.1.5 rules for sharing confidential information, on the initiative of the EU reference laboratory, with a competent authority of a Member State and with the European Commission where the EU reference laboratory has reason to believe that such sharing is in the interest of protection of public health | document(s) name: | yes no |  |
| 11.1 | Confirmation by the Member States regarding the performance of tasks in the public interest and in an independent manner | document(s) name: | yes no |  |
| 13.1 | Declaration of independence of the candidate laboratory | Candidate declaration  Member State visa  document(s) name: | yes no |  |
| 14.1 | List of requirements regarding the tasks covered by the contract | If applicable:  document(s) name: | yes no |  |