Annex XI

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

Nominating Member State: ……..

Competent authority: …….

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: □ Yes □ No

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 (column n.4 of the table below).

For consortia applications: one verification table needs to be completed and submitted for each candidate laboratory applying as part of the consortium by the Member State where it is located.

Criterion No	**Means of proof**	**MS verification of supporting documents[1]**	**MS granted presumption of conformity for the following Articles of Regulation (EU) 2022/944 to the EN ISO/IEC 17025 accredited candidate laboratory[2]**	**Justification/ Comments - if any**
-	Certificate of accreditation according to EN ISO/IEC 17025	If applicable: □	N/A	
-	Accession letter[3]	If applicable: □	N/A	
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)	
3.1	Estimate of minimum capacity regarding performance	□	N/A	

[1] Tick to confirm that means of proof has been provided, or MS visa was granted, where required
[2] Applicable only for candidate laboratories accredited to EN ISO/IEC 17025: tick box to grant presumption of conformity in accordance with Article 8 of Regulation (EU) 2022/944
[3] Applicable only for consortia; each member of a consortium must submit an accession letter

	verification			
3.2	Estimate of minimum capacity regarding batch testing	□	N/A	
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)	
5.1	Justification regarding equipment and reference materials	□	N/A	
5.2	Evidence of possession of equipment and reference materials	□	□ Article 2(1), point (b)	
5.3	Plan for procurement of specimens, control materials and reference materials	□	N/A	
6.1	List of international standards and best practices, including common specifications	□	N/A	
6.2	Evidence of integration international standards and best practices, including common specifications	□	N/A	
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	□		
9.1	Evidence of the laboratory's status as a legal entity	□	□ Article 4(3), point (a)	
9.2	If the laboratory is part of a larger organisation, information related to that larger organisation	If applicable: □	N/A	
9.3	If the laboratory is, directly or indirectly, controlled by other entities, the identity of such entities and their controlling position	If applicable: □	N/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)	
9.6	Evidence of sources of funding	□	N/A	
9.7	Declaration on honour regarding exclusion criteria	□ □ MS visa	N/A	
9.8.1	Economic viability template	□	N/A	
9.8.2	Balance sheets, profit and loss accounts or annual reports for the last three financial years	□	N/A	
9.8.3	Audits reports from the last	Where	N/A	

	three financial years	available: □		
9.9	Proposed system for records of costs and fees	□	N/A	
10.1	Confidentiality policy including the following:	□	N/A	
	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)	
	10.1.4 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	□	N/A	
	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	□	N/A	
10.2	List of measures to ensure that the staff complies with the confidentiality policy	□	□ Article 5(2)	
11.1	Confirmation by the Member States regarding the performance of tasks in the public interest and in an independent manner	□	N/A	
12.1	Policy for the management of conflict of interest	□	□ Article 6(2)	
13.1	Declaration of independence of the candidate laboratory	□ □ MS visa	N/A	
14.1	List of requirements regarding the tasks covered by the contract	If applicable: □	N/A	
14.2	Declaration regarding the external laboratories	If applicable: □	□ Article 7(3), point (a), (b), (c)	