

## Annex V

### **Declaration on honour regarding exclusion criteria (point 9.7 of the selection criteria)**

Full official name of the candidate laboratory: .....

Full address of the candidate laboratory: .....

I, the undersigned, [*insert name*]....., [*insert function of the undersigned in the laboratory*]....., and thus legally authorised representative of the abovementioned laboratory vis-à-vis third parties and acting on behalf of that laboratory,

in the context of the call for applications for designation of EU reference laboratories in the field of *in vitro* diagnostic medical devices according to Article 100 of Regulation (EU) 2017/746,

declare that the candidate laboratory mentioned above is not in any of the following situations for exclusion set out in Article 136 of Regulation (EU) 2018/1046<sup>1</sup>:

(a) the person or entity is bankrupt, subject to insolvency or winding-up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended, or it is in any analogous situation arising from a similar procedure provided for under Union or national law;

(b) it has been established by a final judgment or a final administrative decision that the person or entity is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;

(c) it has been established by a final judgment or a final administrative decision that the person or entity is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person or entity belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:

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<sup>1</sup> Regulation (EU, Euratom) 2017/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012

- (i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of eligibility or selection criteria or in the implementation of the legal commitment;
- (ii) entering into agreement with other persons or entities with the aim of distorting competition;
- (iii) violating intellectual property rights;
- (iv) attempting to influence the decision-making of the authorising officer responsible during the award procedure;
- (v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;

(d) it has been established by a final judgment that the person or entity is guilty of any of the following:

- (i) fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 of the European Parliament and of the Council and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;
- (ii) corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or active corruption within the meaning of Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA, or corruption as defined in other applicable laws;
- (iii) conduct related to a criminal organisation as referred to in Article 2 of Council Framework Decision 2008/841/JHA;
- (iv) money laundering or terrorist financing within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council;
- (v) terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;
- (vi) child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;

(e) the person or entity has shown significant deficiencies in complying with main obligations in the implementation of a legal commitment financed by the budget which has:

- (i) led to the early termination of a legal commitment;
- (ii) led to the application of liquidated damages or other contractual penalties; or
- (iii) been discovered by an authorising officer, OLAF or the Court of Auditors following checks, audits or investigations;

(f) it has been established by a final judgment or final administrative decision that the person or entity has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;

(g) it has been established by a final judgment or final administrative decision that the person or entity has created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration or principal place of business;

(h) it has been established by a final judgment or final administrative decision that an entity has been created with the intent referred to in point (g).

Full name:

Date:

Signature:

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Visa of the Member State where the laboratory is located:

Member State:

Name of competent authority:

Name of contact person:

Signature:

Date: