

Annex VII

Declaration of independence of the candidate laboratory (point 13.1 of the selection criteria)

Full 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, if designated, will not:

1. be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices within the proposed scope of designation, nor the authorised representative of any of those parties;
2. be involved in the design, manufacture or construction, marketing, installation, use or maintenance of the devices within the proposed scope of designation;
3. be a notified body for devices within the proposed scope of designation;
4. perform any tasks related to conformity assessment under Regulation (EU) 2017/746 on request of a notified body, other than the tasks referred to in Article 100(2) of Regulation (EU) 2017/746, within the scope of designation of the laboratory.
5. enter into collaboration with a device manufacturer or a notified body concerning a joint commercial exploitation, if such collaboration falls within the scope of its designation.

Full name:

Date:

Signature:

Visa of the Member State where the laboratory is located:

Member State:

Name of competent authority:

Name of contact person:

Signature:

Date: