**Manufacturers Statement of Compliance for a in vitro diagnostic medical device for performance study**

Manufacturer:

In vitro diagnostic medical device in performance study (name, model):

Performance Study Plan title:

Performance Study reference no. / ID no.:

The manufacturer of the above device for performance study hereby confirms that the device for performance study in question conform(s) to the applicable general safety and performance requirements set out in Annex I of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, apart from the aspects covered by the clinical performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects.

Date:

Signature

Name

Title

(Representative from manufacturer’s management)