**Statement of Conformity with General Safety and Performance Requirements (GSPR)**

**Investigational In-Vitro Diagnostic Medical Device**

Declaration by the manufacturer regarding conformity to GSPR for investigational In-vitro diagnostic medical devices (IVD).

Manufacturer:

IVD medical device under investigation:

Clinical performance study plan (CPSP):

Clinical performance reference no. / ID no (e.g., CPSP ID):

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The manufacturer of the above investigational device hereby confirms that the device in question complies to the General Safety and Performance Requirements (GSPR) set out in Annex I of the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746, apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

Date:

Signature:

Name:

Title\*:

\* The statement must be dated and signed by the managing director or regulatory affairs manager or manager responsible for compliance with the general safety and performance requirements.