[To be printed on Letterhead of Manufacturer]

Composition Certificate

We hereby declare that the composition of the in-vitro diagnostic medical device *< Please add product name (without listing codes/catalogue numbers unless needed to identify the product) as it appears in the Declaration of Conformity / CE / Free Sale Certificate / CFG / Canadian Medical Device Active License>* **is listed in the below table:**

< Please fill in the below table according to chosen Raw Material type;
- When "Component" is chosen, please complete the info "Raw Material Component Name" and "Raw Material" and add "N/A" in the rest of columns or delete them as applicable
- When "Active ingredient" or "Inactive ingredient" is chosen as raw material type, please add "N/A" in the column "Raw Material Component Name" or delete it, and complete the info in the rest of the columns >
< If the composition is variable for each variant, please add the composition for each variant as applicable >
< Please clarify any added abbreviations>

Raw Material Type *(Please choose either Component, Active ingredient or Inactive ingredient)*	**Raw Material Component Name** *(Please add component name of the product where applicable)*	**Raw Material** *(Please add raw material name of the listed Component, Active ingredient or Inactive ingredient)*	**Raw Material Concentration** *(Please add raw material concentration where applicable)*	**Raw Material Role** *(Please add raw material role where applicable)*	**Raw Material Activity** *(Please add raw material Activity where applicable)*