[To be printed on Letterhead of Manufacturer]

Technical File for IVD Product Registration

[To be printed on Letterhead of Manufacturer]
[for each product]

Name and Address of Manufacturer (Legal & Actual Manufacturers if present)
< Please add Manufacturer Name >
< Please add Manufacturer Address >

Technical File Name: *< Please add the name of the technical file and mention it in the footer of each page in the document>*

Technical File Version: *< Please state the version number of the technical file and mention it in the footer of each page in the document>*

Statement of legal liability

We hereby declare that 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 in conformity with the following legislative acts** *< Please state the Adopted Regulation applied>* **and that all supporting documentation is retained under the control of the legal manufacturer.**

Product Description

< Please fill in the below table>

IVD Product List of Variants	*< Please add codes, catalogue numbers or package sizes "if this is the type of variant" that are applied for registration as it appears in the Declaration of Conformity / CE / Free Sale Certificate / CFG / Canadian Medical Device Active License>*
Intended use	*< Please type the intended use as it appears in the instruction for use>*
IVD Kit Components	*< Please describe the content of the IVD product/Kit as it appears on the labels>*