



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 >