

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) |
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