Packaging Certificate

The Packaging configuration(s) 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 table below:**

< Please fill all possible packaging configurations in the below table >
< If any packaging level doesn't apply on the product or is not labelled with product info (such as shipper pack), please delete its relevant rows>
< If number of units in Secondary packaging level and/or Tertiary packaging level is variable according to customer request, please add this fact in Packing Description row and delete the row(s): Secondary Pack Number of Units and/or Tertiary Pack Number of Units as applicable >
< If number of units in Secondary packaging level and/or Tertiary packaging level is variable according to variant, please add the no. of units/relevant packaging level for each variant /group of variants in packing description section and delete the row(s): Secondary Pack Number of Units and/or Tertiary Pack Number of Units as applicable >
< Please clarify any added abbreviations >

Packing Description	*(Please describe the packaging configuration of the product including primary, secondary and tertiary packaging levels as applicable.* *(Please clarify if IFU, patient labels, desiccant, etc. are included)* *(Please clarify if the packaging configuration include an accessories pack (e.g., swab, dropper) and define in which packaging level it is present)*
Material of Primary Pack	*(Please describe primary packaging components and clarify their materials) (Primary packaging is the packaging in direct contact with the product itself. This is the first layer containing the finished product)*
Primary Pack Number of Units	*(Please clarify no. of units per primary pack)*
Material of Secondary Pack	*(Please describe Secondary packaging components and clarify their materials) (This type of packaging is used outside of primary packaging to group a certain number of products e.g., box)*
Secondary Pack Number of Units	*(Please clarify no. of units per Secondary pack)*
Material of Tertiary Pack	*(Please describe Tertiary packaging components and clarify their materials) (Tertiary packaging is referred to as bulk or transit packaging, this type of packaging is used to group larger quantities of secondary packaging)*

Tertiary Pack Number of Units	*(Please clarify no. of units per Tertiary pack)*
Number of Units Per Pack	*(Please clarify no. of units per sales pack)*