MANUFACTURER'S DECLARATION OF CONFORMITY

[To be printed on Letterhead of Manufacturer]

We hereby declare, under our responsibility that the in-vitro diagnostic medical device specified below complies with the essential requirements of the European Union In-Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC) as amended and current relevant regulations and guidelines in Egypt.

Manufacturer's Name/Trade Name: *(as appears on label)*	*< Please add name of the manufacturer (facility) responsible for placing the device on Egyptian market >*	
Manufacturer's address: *(as appears on label)*	*< Please add complete address of the manufacturer >*	
Medical device: *(as appears on label)*	*< The unique product identifier (for example the device name, device description and model number(s)/catalogue number(s)/REF) > < OR "See attached Product List" >*	
Intended Use: *(as appears in IFU where applicable)*	*< please provide intended use of the device > < OR "See attached IFUs in case of multiple products in the same DOC" >*	
Manufacturing Site(s):	*< please provide name and address of physical manufacturing site(s) (where applicable) >* *< OR please remove this section if all manufacturing processes take place in the facility entered in* Manufacturer's Name/Trade Name *and Manufacturer's address sections >*	
Quality Management System Certificate (ISO 13485:2016): *< please provide requested certificate info for all devices classified Self-Testing, Annex II list B or Annex II list A as per IVDD 98/79/EC as amended >* *< OR please remove this section for devices classified as General >*	**Certification Body Name**	*< Please add the name of the certification body >*
	Certificate Number	*< Please add the number of ISO certificate >*
	Issue Date	*< Please add the issue date of ISO certificate >*
	Expiry Date	*< Please add the expiry date of ISO certificate>*
CE Certificates *< please provide requested certificate info for all devices classified Self-Testing, Annex II list B or Annex II list A as per IVDD 98/79/EC as amended >* *< OR please remove this section for devices classified as General as per IVDD 98/79/EC >*	**Notified Body Name**	*< Please add the name of the notified body >*
	Certificate Number	*< Please add the number of CE certificate >*
	Issue Date	*< Please add the issue date of CE certificate >*
	Expiry Date	*< Please add the expiry date of CE certificate >*

Risk classification *< e.g., Class X, rule X >*	*< Please provide the class of the device (Class General, Self-Testing, Annex II list B or Annex II list A) according to classification rules listed in IVDD 98/79/EC as amended >*
Justification of risk classification	*< Please provide clarification on how the classification rules listed in annex II, IVDD 98/79/EC as amended >*
Nomenclature code, type and term:	*< Please Specify nomenclature code type (for example GMDN, UMDNS, EMDN, etc.), include code and term >*
Additional European directives/Laws applicable on the product	*< Please give details of any additional European directives/Laws applicable on the product >* *< OR please remove this section if not applicable >*
Standards applied:	*< Please give details of any International, harmonized, regional or national standards, Common Specifications (CS) that have been applied to the product(s) >* *< OR "See attached Applied Standards list" (for multiple standards) >*

< Please Clarify the new classification of the product according to the new European Regulation (IVDR) as this is required to facilitate grouping of general IVD products applied for Registration >
This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until the end of transitional period stipulated in REGULATION (EU) 2017/746 & its related regulations. The Classification of this product under REGULATION (EU) 2017/746 is *< Class B, C or D >*

Signed on behalf of *< Please add manufacturer name>***,**

Authorized signatory: *< To be signed by the person authorized by the manufacturer >*		
< please add authorized signatory name and title >	*< Please apply signature and manufacturer stamp >*	*< Please add place and date of applying signature>*
Name & Position	***Signature & Stamp***	***Place, Date***

Issue Date: *DD/MM/YYYY*

- Lines in blue are for clarification purpose only and to be deleted in the signed document.
- Wording in green between marks " " may be used where applicable.