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 General Safety and Performance requirements of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on IVD medical devices 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 >*	**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 Class B, C or D as per REGULATION (EU) 2017/746 as amended >* *< OR please remove this section for devices classified as Class A as per REGULATION (EU) 2017/746 >*	**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 A, B, C or D) according to classification rules listed in REGULATION (EU) 2017/746 as amended >*
Justification of risk classification	*< Please provide clarification on how the classification rules listed in annex VIII, REGULATION (EU) 2017/746 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) >*

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.