



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 >	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 >



< OR please remove this section for devices classified as Class A as per REGULATION (EU) 2017/746 >	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.