



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	Notified Body Name	< Please add the name of the notified body >
	Certificate Number	< Please add the number of CE certificate >



per IVDD 98/79/EC as amended > < OR please remove this section for devices classified as General as per IVDD 98/79/EC >	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 >
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Name & Position	Signature & Stamp	Place, Date
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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.