MANUFACTURER'S DECLARATION OF CONFORMITY

[To be printed on Letterhead of Manufacturer]

We hereby declare, under our responsibility that the medical device specified below complies with the essential requirements, the provisions of regulation (EU) 2017/745 of the European Parliament

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 registered place >*
Manufacturer's SRN	*as referred to in Article 31 to be added by 28-05-2026*
Authorized representative 's Name *(as appears on label)*	*< Please add name of authorized representative >*
Authorized representative 's address: *(as appears on label)*	*< Please add complete address of authorized representative registered place >*
Authorized representative 's SRN	*as referred to in Article 31 to be added by 28-05-2026*
Medical device: *(as appears on label)*	*Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate* *< OR "See attached Product List" >*
Basic UDI-DI	The Basic UDI-DI as referred to in Part C of Annex VI; *< OR "See attached Product List" >*
Intended Use: *(as appears in IFU where IFU IS applicable)*	*< please provide intended use of the device >*
Manufacturing Site(s):	*< please provide name and address of physical manufacturing site(s) including sterilization site(s) (where applicable) with their roles >* *< OR please remove this section if all manufacturing processes and sterilization take place in the facility entered in* Manufacturer's Name/Trade Name *and Manufacturer's address sections >*

Quality Management System Certificate (ISO 13485:2016): **<u>If applicable</u>**	**Certification Body Name**	
	Certificate Number	
	Issue Date	
	Expiry Date	
CE certificate/s *< please provide requested certificate info for all devices classified I sterile, I reusable, I measuring, IIa, IIb, or III>*	**Notified Body Name**	
	Notified Body ID number	
	Description of the conformity assessment procedure performed	
	Certificate Number/s	
	Issue Date/s	
	Expiry Date/s	
Risk classification *< e.g. Class X, rule X >*	*< Please provide the class of the device (Class I sterile, I measuring, I non- sterile, IIa, IIb, or III) according to classification rules listed in regulation (EU) 2017/745 of the European parliament*	
Justification of risk classification	*< Please provide clarification on how the classification rules listed in annex VIII & relevant EU Directives (Directive 2003/12/EC, Directive 2005/50/EC, etc.) apply on the device >*	
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; e.g.: Commission Regulation (EU) No 722/2012 >* *< OR please remove this section if not applicable >*	
Common Specification (CS)	*References to any CS used and in relation to which conformity is declared; Where 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) >*
additional information	*Where applicable,*

The device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

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

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

- 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.