Ref No	Rev No.	Issue Date

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 Medical Device Directive 93/42/EEC as amended and EDA regulations.

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 descriptionand model number(s)/catalogue number(s)/REF)>* *<OR "See attached Product List">*	
Intended Use: *(as appears in IFUwhere 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): *<please provide requested certificate info for all devices classified I sterile, I measuring,IIa, IIb, or III as per MDD 93/42/EEC as amended& relevant EU Directives as well as devices in dosage forms>* *<OR please remove this section for devices classified as I non-sterile as per MDD 93/42/EEC*	**Certification BodyName**	
	Certificate Number	
	Issue Date	
	Expiry Date	

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other than those in dosage form >		
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 MDD 93/42/EEC as amended & relevant EU Directives (Directive 2003/12/EC, Directive 2005/50/EC, etc.)>*	
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 >*	
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>*

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.

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