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 current relevant regulations and guidelines in Egypt.

<table>
<tr><td>Manufacturer's Name/Trade Name:
(as appears on label)</td><td colspan="2">< Please add name of the manufacturer (facility) responsible for placing the device on Egyptian market ></td></tr>
<tr><td>Manufacturer's address:
(as appears on label)</td><td colspan="2">< Please add complete address of the manufacturer ></td></tr>
<tr><td>Medical device:
(as appears on label)</td><td colspan="2">< The unique product identifier (for example the device name, device description and model number(s)/catalogue number(s)/REF) >
< OR "See attached Product List" ></td></tr>
<tr><td>Intended Use:
(as appears in IFU where applicable)</td><td colspan="2">< please provide intended use of the device ></td></tr>
<tr><td>Manufacturing Site(s):</td><td colspan="2">< 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 ></td></tr>
<tr><td rowspan="4">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 other than those in dosage form ></td><td>Certification Body Name</td><td></td></tr>
<tr><td>Certificate Number</td><td></td></tr>
<tr><td>Issue Date</td><td></td></tr>
<tr><td>Expiry Date</td><td></td></tr>
<tr><td>Risk classification
< e.g. Class X, rule X ></td><td colspan="2">< 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.) ></td></tr>
</table>

Justification of risk classification	*< Please provide clarification on how the classification rules listed in annex IX, MDD 93/42/EEC as amended & 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 >*
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.
- Wording in green between marks " " may be used where applicable.