التعهدات الخاصة بمأمونية المستلزمات الطبية
(COMPANY NAME)
(Date)

MANUFACTURER'S COMMITMENT ABOUT SAFETY OF MEDICAL DEVICES

Declaration (1)

For MDs Class I and IIa

Dear Head of Central administration for medical devices,

Dear Head of Medical Devices Registration Department,

For the following medical device applied for registration/re-registration/variation of marketing authorization in the Arab Republic of Egypt:

- **Medical Device Acceptance Number:**
- **Medical Device Name:**
- **Medical Device Models/Codes/Sizes:**

- (Company) undertakes that the medical device applied for registration/re-registration/variation, which will be marketed in the Arab Republic of Egypt, has not received any regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) in respect of (Models/Codes/Sizes, Lots/Batches, or Serials), in an interval of (3) three years before the date of application for registration/re-registration/variation.
- (Company) undertakes that in case of any regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) raised after the application for registration/reregistration/variation and before granting the marketing authorization of the medical device, those regulatory actions concerning the safety of the medical device in respect of (Models/Codes No., Lot/Batch No., or Serial No.) will be informed to the "Medical Devices Registration Department" and communicated to the "Medical Device Safety Department (MDSD - EPVC)" by (Agent) - the company's agent in the Arab Republic of Egypt.
- (Company) undertakes that since granting the marketing authorization of the medical device and during the marketing stage, (Company) will be obliged to communicate any incidents (MIRs), Periodic Summary Reports (PSRs), or regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) to the "Medical Device Safety Department (MDSD - EPVC)" by (Agent) - the company's agent in the Arab Republic of Egypt, this is according to the Egyptian Guidelines for Medical Device Vigilance System.
- (Company) undertakes that there is a vigilance system in place, oversights the vigilance system of the (Agent) - the company's agent in the Arab Republic of Egypt, and makes sure that (Agent) meets all vigilance requirements (in reference to the Egyptian Guideline for Medical Device Vigilance System), and communicates them with the "Medical Device Safety Department (MDSD - EPVC)".

Signature

Title

(Date)

في حالة وجود ممثل قانوني للمصنع القانوني يتم تقديم التعهدالآتي:

(COMPANY NAME)
(Date)
Manufacturer's Commitment About Safety Of Medical Devices
For MDs Class I and IIa

Declaration (1)

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Signature

Title

(Date)

<u>في حالة وجود ممثل قانوني للمصنع القانوني يتم تقديم التعهد الآتي:</u>

COMPANY NAME
Date
Manufacturer's Commitment about Safety of Medical Devices

Declaration (2)

Class IIb, III, AND (I, IIa with Regulatory Actions)

Dear Head of Central administration for medical devices,

Dear Head of Medical Devices Registration Department,

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Signature

Title

(Date)

COMPANY NAME

Date

Manufacturer's Commitment about Safety of Medical Devices

Declaration (2)

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Signature

Title

(Date)

[COMPANY NAME]
(Date**)**

Dear Head of the Egyptian Pharmaceutical Vigilance Center,

Dear Head of Medical Devices Safety Department,
The following is the list of contacts of safety responsible(s):

No.	Name of The Local Safety Responsible(s)	Title	Name of the Department	Email	Phone Number	Mobile Number

Signature

Title

(Date**)**