Appendix VIII

أولاً: متطلبات المأمونية بالنسبة للكواشف المعملية والتشخيصية :

General, Self-Testing IVDs ** و لم يحدث له إجراءات رقابية
تلتزم الشركات بتقديم التعهد (مرفق) الذي يرسله المصنع القانوني (Legal Manufacturer) لإدارة الكواشف المعملية والتشخيصية بالإدارة المركزية للمستلزمات الطبية مباشرة بالبريد المسجل وليس عن طريق الوكيل، ولا يتم استصدار خطاب تحويل لها للتوجه لإدارة المأمونية.

جميع List A, B IVDs , و General, Self-Testing IVD s حدث لها إجراءات رقابية في فترة (3) ثلاثة أعوام سابقة لتاريخ التقديم

تلتزم الشركات بالتوجه لإدارة المأمونية بموجب خطاب التحويل من إدارة الكواشف المعملية والتشخيصية بالإدارة المركزية للمستلزمات الطبية لتقديم المستندات المطلوبة لتقييم المأمونية في إطار التسجيل/إعادة التسجيل/متغيرات (والتي تتضمن ملخص تاريخ التسويق)

- تقديم التعهد المطلوب (مرفق)، على أن يتم إرساله بواسطة المصنع القانوني (Legal Manufacturer) لإدارة الكواشف المعملية والتشخيصية بالإدارة المركزية للمستلزمات الطبية مباشرة بالبريد المسجل وليس عن طريق الوكيل

ثانياً: متطلبات المأمونية للشركات (غير مرتبط بالتسجيل):

1. تلتزم الشركات بتقديم نظام اليقظة الخاص بمقدم الطلب(Vigilance System)
2. تلتزم الشركات بتعيين مسئول يقظة بمقدم الطلبأو إضافة مهامه لمسئول الشئون الرقابية وتقديم خطاب ترشيحه (Nomination Letter) لإدارة المأمونية.
3. تلتزم الشركات بدفع مقابل خدمات عند تقديم ملفاتها لإدارة المأمونية.
4. تلتزم الشركات بأي مستجدات بخصوص متطلبات المأمونية (إن وجدت).

[COMPANY NAME]

(Date)

MANUFACTURER'S COMMITMENT ABOUT SAFETY OF IVDS

Declaration (1)

For IVDs Class (General, Self-Testing IVDs)

Dear Head of Medical Devices Unit,

Dear Head of IVDs Department,

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

- **IVD Acceptance Number:**
- **IVD Name:**
- **IVD Models/Codes/Sizes:**

- (Company) undertakes that the IVD 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 IVD, those regulatory actions concerning the safety of the IVD in respect of (Models/Codes No., Lot/Batch No., or Serial No.) will be informed to the "IVDs 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 IVD 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)

[COMPANY NAME]

(Date)

MANUFACTURER'S COMMITMENT ABOUT SAFETY OF IVDS

Declaration (2)

For IVDs Class (List A, B IVDs) and (General, Self-Testing IVDs with Regulatory Actions)

Dear Head of Medical Devices Unit,

Dear Head of IVDs Department,

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

- **IVD Acceptance Number:**
- **IVD Name:**
- **IVD Models/Codes/Sizes:**

- (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 IVD, those regulatory actions concerning the safety of the IVD in respect of (Models/Codes No., Lot/Batch No., or Serial No.) will be informed to the "IVDs 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 IVD 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)