Regulatory Rules of

Registration and Market authorization of

In Vitro Diagnostic Medical Devices

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1. Introduction:

These regulatory rules concerning the rules and procedures for local and imported in vitro diagnostic and medical device, approved by the Egyptian Drug Authority in accordance with the law establishing the Authority promulgated by the Law No. (151) of 2019.

2. Definitions:

- **In vitro diagnostic and medical device according to the European directive 98/79/EC**

'**In vitro diagnostic medical device**` means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used as in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- Concerning a physiological or pathological state,
- Concerning a congenital abnormality,
- Determining the safety and compatibility with potential recipients, or
- Monitoring therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices.

'Specimen receptacles` are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

- **Locally manufactured in vitro diagnostic medical device**: It means the laboratory and in vitro diagnostic reagents that are manufactured in factories within the Arab Republic of Egypt.
- **Imported in vitro diagnostic medical device:** It means the laboratory and in vitro diagnostic reagents manufactured abroad.
- **Applicant**:

A. A local factory manufacturing in vitro diagnostic medical device.

B. Scientific office or distributer / agent for the foreign company for imported in vitro diagnostic medical device.

- **The Reference Countries**: Australia, Canada, European Union countries, Iceland, Japan, New Zealand, Norway, Switzerland, United Kingdom and USA.
- **Pilot Batch**: Trial operation.
- **GSP**: Good Storage Practices
- **Marketing License**: It is an approval issued by the Egyptian Drug Authority to sell, market and circulate in vitro diagnostic medical devices within the Arab Republic of Egypt after reviewing the supportive documents of the product.

3. Appling procedures for registration of in vitro diagnostic medical devices:

A. Evaluating the request and registering the in vitro diagnostic medical devices:

- In the case of imported and local in vitro diagnostic medical devices that have obtained international quality certificates like their imported equivalents as shown in (Appendix III) according to the different classifications, the following procedures shall be applied:
- The imported in vitro diagnostic medical device shall be circulated in the country of origin or one of the approved reference countries.
- The registration request for in vitro diagnostic medical devices shall be submitted according to the application form for registration of in vitro diagnostic medical device.
- The applicant shall be obligated to submit the registration file according to the check list of documents for registration of in vitro diagnostic medical devices.
- The file shall be examined by the Reception Department and if the file was fulfilling the required basic documents, it shall be transferred for study and evaluation, provided that the evaluation shall be completed within 20 working days from the date of accepting the file.
- In case of there are documents required to be fulfilled, the applicant shall be notified of them in order to complete the registration file within a maximum period of 60 working days. In case of failure to complete the registration file within this grace period, the applicant may submit a request for another additional grace period of 30 working days.

In case of not fulfilling the required documents of registration file within this period, the request shall be considered never filed.

- The documents that have been fulfilled by the applicant shall be reviewed within 10 working days from the date of their submission, provided that a report on the technical file shall be issued within five working days as follow.
- In the case of local in vitro diagnostic medical devices that haven't obtained any international quality certificates:
- The registration request for in vitro diagnostic medical device shall be submitted according to the request form designated for registration of in vitro diagnostic medical devices. Then the applicant shall be notified of receiving the request within five working days.
- The applicant shall be obligated to import the raw materials used in manufacturing of the in vitro diagnostic medical device after obtaining the approval of the Central Administration of Medical Devices or submitting evidence indicating that the applicant purchased such raw material from the local market. Likewise, in the case of free zone factories: the applicant shall be obligated to submit evidence indicating that he imports the raw materials used in manufacturing of the in vitro diagnostic medical device or purchased them from the local market.
- The applicant shall be obligated to address the Department of In Vitro Diagnostic Medical Device within 20 working days from the date of receiving response of the Central Administration of Medical Devices of acceptance the submitted application, then the following procedures shall be applied:
  - Making sure that the factory adheres to the technical requirements of the place of manufacturing, within 20 working days from the date in which the factory addressed the Department of In Vitro Diagnostic Medical Device where the applicant shall be informed of the required corrective measures, provided that shall complete the technical requirements of the manufacturing place within a maximum of 120 working days. In case of failure to complete the corrective measures within 120 working days, the factory may submit a request for another

additional grace period of 40 working days after which a technical report on the factory shall be issued.

- The factory shall produce a Pilot Batch, provided that this batch shall be never circulated in the local market and the registration procedures and required studies shall be completed.

- Samples shall be withdrawn by the pharmacist of inspection from the pilot batch to be analyzed at the Egyptian Drug Authority's laboratories, provided that the analysis file containing the documents and attachments required for the file shall be submitted by the registration applicant to the Egyptian Drug Authority. The Authority's laboratories shall be obligated to issue the analysis result within 30 working days from the date of completing the analysis file.
- The applicant shall be obligated to submit the registration file within one year from the date in which he received the response of the Central Administration of Medical Devices in accordance with the registration documents list of local in vitro diagnostic medical device that haven't obtained any international quality certificates. The registration file shall include the analysis conformity issued by the Egyptian Drug Authority, in addition to the factory's technical report.
- The file shall be examined by the Reception Department. In the case of the basic required documents of the file was fulfilled, the file shall be transferred for study and evaluation by the Registration Department, provided that the evaluation shall be completed within 20 working days. In case of there are documents required to be completed, the applicant shall be notified with them to be fulfilled within 90 working days as a maximum and in case of failure to fulfill the registration file within this grace period, the applicant may apply for an additional grace period of 30 working days, but in case of failure to complete the registration file during that period, the request shall be considered never filed.
- The documents that have been fulfilled by the applicant shall be reviewed within 10 working days from the date of their submission, provided that a report on the technical file shall be issued within five working days.

B. Issuance of marketing license:

The technical reports of the in vitro diagnostic medical device shall be presented to the Technical Committee of Medical Devices and In Vitro Diagnostic and Medical Device for evaluation. In case of approval, a valid for 5 years marketing license for the in vitro diagnostic medical device shall be issued. The companies shall be obligated to analyze the first three batches produced or imported after the issuance of the marketing license and the batch shall be released after the issuance of the result of the analysis.

C. Marketing License Renewal:

- The in vitro diagnostic medical devices shall be re-registered every 5 years based on a request submitted to the Central Administration of Medical Devices during the last 6 months of the validity of the marketing license.
- The applicant shall be obligated to submit a re-registration file containing a summary of marketing history.
- In case of the in vitro diagnostic medical device has no variations, it shall be presented to the Medical Device Registration Committee. In case of approval by the Medical Device Registration Committee, the marketing license shall be issued.
- In case of the in vitro diagnostic medical device has variations, it shall be evaluated by the Central Administration of Medical Devices according to the procedures applied based on the type of the variations, then it shall be presented to the Medical Device Registration Committee. In case of approval, the marketing license shall be issued.

- The applicant shall be obligated to complete the re-registration procedures within a year from the expiry date of the marketing license. The applicant may circulate the recant during this period. Upon the expiry of this period and the failure to meet the requirements of the final re-registration file, the in vitro diagnostic medical device shall obtain an additional grace period of six months to complete the requirements of the final re-registration file but the production or importing of the medical device shall be suspended. in case of failure to fulfill the requirements of the final re-registration file within the additional six months, the request shall be considered never filed.

D. Issuing an import approval for in vitro diagnostic medical devices to allow their circulation:

- An annual import approval shall be issued for each foreign factory separately without identifying of the item's quantities for the applicant imports.
- The applicant shall be obligated to submit the renewed certificates (for expired or invalid certificates) during the validity period of the annual import approval to keep them valid.
- The precautional release shall be issued for each invoice separately.
- It shall be allowed to issue an import approval for each invoice separately in the case of this is required for items not included in the annual import approval.

4. General requirements:

The applicant shall be obligated to apply the following:

- Printing the factory name, address, expiry date, batch number and registration number on the outer packaging. In the case of imported in vitro diagnostic medical devices, printing the legal manufacturer name, country of origin, expiry date, batch number and registration number.
- Not to make any variation in the in vitro diagnostic medical devices except after obtaining an approval of the Central Administration of Medical Devices in accordance with the procedures followed pursuant to the variable type, otherwise the marketing license shall be null and void.
- Using the same source of the raw material from which the pilot batch was manufactured and on which all the required studies were conducted for the locally manufactured in vitro diagnostic medical devices. The sources of effective raw materials shall not be changed except after obtaining an approval of the Central Administration of Medical Devices to re-evaluate the supplier, otherwise the marketing license shall be cancelled
- Applying the Recall System.
- Submission of the documents of the importing IVDs to obtain an import approval.
- For the items that have not been previously circulated- it shall be allowed to be circulated for a period of 6 months without obtaining the marketing license, provided that the applicant shall apply for obtaining the marketing license before the end of the 6-months grace period which starts from the date of issuance of the first import approval for the imported product or from the date of production of the first batch of the local in vitro diagnostic medical devices, as the case may be.
- Applicant obligated to apply the vigilance requirements.
- Factories obligated to print following QR Code which shows the electronic link for reporting any patient or user problems, usability or quality problems to the Egyptian Drug Authority.

5. Appendixes:

Appendix I	Application form for the registration of in vitro diagnostic laboratory in vitro diagnostic medical devices.
Appendix II	Check list of documents for the registration of locally manufactured in vitro diagnostic laboratory in vitro diagnostic medical devices that haven't obtained any international quality certificates.
Appendix III	Technical documentation details according to the classification
Appendix IV	Check list of documents for the registration of imported & local manufactured in vitro diagnostic laboratory in vitro diagnostic medical devices that have obtained international quality certificates
Appendix V	Check list of IVDs importation approval
Appendix VI	The Necessary Requirements for In Vitro Diagnostic Medical Devices Manufacturers
Appendix VII	Application form for re-reg of IVD
Appendix VIII	Vigilance Requirements

Appendix I

Appendix I Application form for the registration of in vitro diagnostic medical devices.

Type of application: local / imported

Applicant name:

Applicant Address:

Applicant Email address:

Applicant Telephone:

Trade name:

Description:

The intended use /Indication:

Legal manufacturer name:

Manufacturing site name: multiple

Manufacturing site address:

Country of origin: multiple

Appendix II

Check list of the locally manufactured in vitro diagnostics registration does not that haven't obtained any international quality certificates.

First: The documents related to-the registration applicant:

1. A numbered list of the content of the registration file.
2. A Receipt of payment for services fees.
3. An official request from the applicant stamped and signed by the manager of the company according to the form published by the department.
4. The factory undertaking to apply the vigilance requirements.
5. The original authorization issued by the manufacturer and approved by the chairman of the Board of directors along with bank authentication of the signature of the person responsible for dealing with the Central Administration of Medical Devices.
6. **Local factories**:

- Commercial register.
- Tax card.
- An operating license issued by the Industrial Development Authority.

Free Zone Factories:

- Commercial register.
- Tax card.
- The license issued by the General Authority for Investment and Free Zones to practice the activity under the free zones system.

Second: Technical documentation

1. Administration:

A. Name of manufacturer
B. Address of manufacturer
C. Address of any associated manufacturing sites
D. Statement of legal liability
E. License of manufacturing No. (attachment)
F. Name of the authorized person
G. Authorized person Delegation Letter (attachment)
H. Name of contact person
I. Tel
J. Fax
K. E-mail
L. Web address

M. 13485:2016, and CE certificate according to IVD, or IVDR If present (attachment)

N. Declaration of conformity / or letter of declaration according to the adopted regulation (attachment)

NB: The adopted regulation to be one of the GHTF member

2. Device description

- Name of the device.
- Brand name.
- Variant: codes, references or sizes.
- Intended use.
- Risk classification according to European regulations (European directive 79/98/ EEC).
- Description of principle of the assay and methodology used.
- Description of individual components included in the IVD.

Where applicable, the following should also be provided:

- A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IV.
- For assays requiring instrumentation, a description of the relevant instrumentation characteristics or details of dedicated instrumentation to be used.
- A description of any software to be used.
- A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.

3. Device history (Transitional State only):

- A summary of the product history in the domestic market and any other countries (attachment).
- A list of countries or regulatory jurisdictions, approximate numbers of IVDs and/or period of time supplied, summary of any adverse events, recalls, corrective/ preventive actions or refusal to approve for supply (attachment)

4. Risk analysis and control summary.

5. Design and/or manufacturing information.

6. Clinical evidence report (if IVDR applied).

7. Clinical summary report (if IVDR applied).

8. Performance evaluation (attachment).

- Diagnostic sensitivity
- Diagnostic specificity

9. Product Validation and Verification (attachment).

i. Specimen type:

- A list of all appropriate specimen type(s) suitable for use with the IVD shall be provided, including anticoagulants, matrices

  NB: Analytical performance study reports should include information about the nature of the specimen types tested (eg, spiked, wild type etc.) and the geographic location where specimens were obtained, as appropriate.

- Any special instructions or conditions associated with specimen collection.
- Specimen stability, appropriate storage conditions and where applicable, transport conditions storage includes elements such as duration, temperature limits, number of freeze/thaw cycles.

ii. Accuracy: = both trueness and precision (Reproducibility and repeatability).

- Reproducibility should include information about studies to estimate total variability and as appropriate, between-day, between-run, between-sites, between-batches, between-operators and between-instrument variability.
- Repeatability should include information about studies to estimate total variability and as appropriate, within-run variability.
- The results of testing should include samples that represent the full range of expected analytic concentrations within the target population.

iii. Analytical sensitivity:

Specimen characterization and number of replicates tasted at each concentration.

- Calculations used to determine the assay sensitivity should be included.

iv. Analytical specificity:

- Information relating to any studies conducted to determine the effect caused by potentially interfering or cross-reacting substances or agents on test results should be provided.
- Consideration should be given to both exogenous and endogenous factors expected to be encountered.

v. Measuring range of assay:

- A summary of the studies conducted to define the assay measuring range should be included for both linear and non-linear systems.
- Information provided should describe the lower limit of detection and how this was determined (eg, product of dilutions, standards, number of replicates) and include an investigation into any potential effects of Prozone or high-dose hook effect, if applicable

vi. Traceability of calibrators and controls:

- Information summarizing the traceability of calibrators and trueness control materials should be provided, if applicable.
- Methods used to determine traceability to reference material of a higher order, acceptance criteria, and the assignment and validation of values should be included.

vii. **Determination of assay cut-off:**

- A summary of the process used to establish the assay cut-off should be provided.
- Information provided should be based on the population studied, method(s) used to establish the true status and any statistical methods used to generate results eg, ROC curve.

viii. **Verification and validation of instrumentation/ software:**

The study report should include a summary of performance testing undertaken conducted in a valid end-user environment

ix. **Stability study.**

10. **Labeling**:

- Inner and outer labels.
- Instructions for use.
- Advertising material (e.g., brochures, web-pages, published advertisements, etc.), where available.

11. **Manufacturing process and control**

Bill of materials, and components

- Certificates of compliance of materials and components from the supplier
- Manufacturer inspection and testing
- Approved suppliers list and supplier evaluation criteria

12. **In process inspection and testing**
13. **Finished product assembly and testing reports**
14. **Product release process and statement of compliance**
15. **Manufacturer testing reports**
16. **Commitment to follow up with medical device PMS**

Appendix III

Technical documentation details according to the classification

	General IVD	Self-testing	List A	List B
1- Administration	Applied for all classes			
• Name of manufacturer				
• Address of manufacturer				
• Address of any associated manufacturing sites				
• Statement of legal liability				
• License of manufacturing no. (attachment)				
• Name of authorized person • Authorized person Delegation Letter (attachment)				
• Name of contact person				
• Tel				
• Fax				
• E-mail				
• Web address				
• 13485:2016, and CE certificate according to IVD, or IVDR If present (attachment)				
• Declaration of conformity / letter of declaration according to the adopted regulation (attachment) • N.B: the adopted regulation to be one of the GHTF member				
2-Device description	Applied for all classes			
• Name of the device				
• Brand name				
• Codes				
• Intended use				
• Risk classification according to European regulation.				
• Description of principle of the assay and methodology used				
• Description of individual components included in the IVD				
• Where applicable, the following should also be provided				
• A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IV				
• For assays requiring instrumentation, a description of				

the relevant instrumentation characteristics or details of dedicated instrumentation to be used				
• A description of any software to be used				
• A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.				
3-Device history (Transitional State only)	Applied for all classes			
4-Risk analysis and control summary	Summary	Summary	Summary	detailed report
5-Design information	Summary	description of the design aspects that make it suitable for lay person use		detailed information on material specifications would be provided.
6-manufacturing information	Summary	Summary	Summary	Summary
7-Clinical evidence report (if IVDR applied)				Detailed
8-Clinical summary report (if IVDR applied)				Detailed
9-Performance evaluation Diagnostic sensitivity Diagnostic specificity	Summary	Summary	Detailed	Detailed
10-Product Validation and Verification (Attachment)				
1.Specimen type	Summary	Summary	Summary	Detailed
2.Accuracy	Summary	Summary	Detailed	Detailed
3.Analytical sensitivity	Summary	Summary	Detailed	Detailed
4.Analytical specificity	Summary	Summary	Detailed	Detailed
5.Measuring range of assay	Summary	Summary	Detailed	Detailed
6.Traceability of calibrator and controls	Summary	Summary	Summary	Detailed
7.Determination of assay cut-off	Summary	Summary	Detailed	Detailed
8.Verification and validation of instrumentation/software				
9.Stability study	Summary	Summary	Detailed	Detailed
10.Labeling	Applied for all classes			
11.Manufacturing process and control	Applied for all classes			
12.In process inspection and testing	Applied for all classes			
Applied for all classes 13. Finished product assembly and testing reports				
14.Product release process and statement of compliance				
15.Manufacturer testing reports				

16.Commitment to follow up with medical device Post-Market Surveillance (PMS).	

Appendix IV

Check list of documents for the registration of imported & local manufactured in vitro diagnostic medical devices that have obtained international quality certificates

First: Documents of the registration applicant:

1. A numbered list of the content of the registration file.
2. A Receipt of payment for the services fees.
3. An official request from the applicant stamped and signed by the manager of the company according to the form published by the department.
4. The manufacturer undertaking commitment to apply the safety mechanisms.
5. The original authorization issued by the applicant and approved by the chairman of the Board of Directors along with the bank authentication of the signature of the person responsible for dealing with the Central Administration of Medical Devices and receiving the marketing license of the in vitro diagnostic medical devices
6. **For the companies, the following documents shall be submitted:**

- The importer registration license containing the name of the manufacturer or the name of the distributing company based on the letter of relationship between the factory and the supplier.
- The direct and valid distribution or agency contract with the foreign supplier (notarized).
- The relationship between the foreign manufacturer and the foreign distributor or supplier, if any. Provided that the text shall expressly indicate the eligibility of the foreign distributing or importing company to conclude contracts and acting as a foreign agent on behalf of the factory (notarized).
- In the of contract is not available during the registration procedures, the applicant shall submit a notarized letter to authorize the importing company to implement the registration procedures, stating the device name, including the trade name of the device, issued by:
  - The legal manufacturer or whosever is delegated by it under a documented relationship; or
  - By the parent company or whosever, it delegates according to a documented relationship (showing the parent company, the legal manufacturer and the entity responsible for issuing the registration authorization, along with the name and address of each of them).

For the scientific offices:

- A Scientific office license.
- A letter (notarized) indicating the relationship between the branches of the foreign company.

For the scientific offices that register the medical devices produced by companies that are not one of the branches of the parent company of the scientific office, shall submit the following documents:

- A certified letter issued by the legal manufacturer of the medical devices authorizing the scientific office to register it in Egypt.

- A certified letter issued by the parent company of the scientific office stating that the company owning the medical devices has no object in authorizing the scientific office to register its devices in Egypt.

For the local manufacturers, in the case of the factory has a certificate of quality and circulation, the following documents shall be submitted:

- The commercial register.
- The tax cards.
- An operating license issued by the Industrial Development Authority.

For free zone manufacturers, in the case of factory that has a certificate of quality and circulation, the following documents shall be submitted:

- The commercial register.
- The tax cards.
- The license issued by the General Authority for Investment and Free Zones to practice the activity under the free zones system.

Second: Circulation and Quality Certificate of the product (in vitro diagnostic medical devices):

1. **Pursuant to the applicable rules of the European community based on the provisions indicated in the "IVD Directive 98/79/EEC":**

Class	Certificates
General IVD Examples: * Tests for hormones * Cardiac markers * Hematology and clinical chemistry tests	1. DOC certificate indicating IVD Directive and classification. 2. "FSC" Free sale certificate issued by the origin country or by one of the reference countries.
IVDs for self -testing Examples: * Pregnancy, cholesterol home test * self-testing devices	1. DOC certificate indicating IVD directive and classification. 2. "FSC" Free sale certificate issued by the origin country or by one of the reference countries. 3. ISO :13485 :2016 certificate. 4. CE III certificate Or CE IV certificate, Or CE V+VI certificate, Or CE V+VII certificate.
IVDs in Annex II List B (Moderate risk) Examples: Rubella, PSA, Self-Test for Blood Glucose strips	1. DOC certificate indicating IVD Directive and classification. 2. "FSC" Free sale certificate issued by the origin country or by one of the reference countries. 3. ISO :13485 :2016 certificate. 4. CE IV certificate, Or CE V+VI certificate, Or CE V+VII certificate
IVDs in Annex II List A (High risk) Examples: HIV, Hepatitis, ABO Blood Grouping	1. DOC certificate indicating IVD Directive and classification. 2. "FSC" Free sale certificate issued by the origin country or by one of the reference countries. 3. ISO:13485:2016 certificate. 4. CE IV certificate, or CE V+VII certificate

2. Pursuant to the applicable rules in the USA based on the provisions indicated in FDA

Class	Certificates
Class I	1. CFG without GMP certificate. 2. The letter of declaration certificate indicating the classification. 3. Code of federal regulation: 21CFR 862, 21CFR 864 or 21CFR 866.
Class II, and III	1. CFG with GMP certificate, or CFG+ISO13485:2016 certificate. 2. The letter of declaration certificate indicating the classification. 3. Code of federal regulation: 21CFR 862, 21CFR 864, 21CFR 866.

3. Pursuant to the applicable rules in Canada:

Class	Required Documents
Class1	1- Declaration letter indicates the full medical device list submitted to the Egyptian Drug Authority. 2- DOC acc. to Canadian regulation indicating the classification. 3- Manufacturer certificate to cover export of medical devices (= FSC) issued from: the (HPFBI), Health Canada. 4- Medical device establishment license.
Class II, III, IV	1- Declaration letter indicates the full medical device list submitted to the Egyptian Drug Authority. 2- Valid license of the medical device (In case of the valid license of the medical device was issued for medical device family, medical device group, or medical device group family) N.B: The declaration letter shall be sent to the health Canada to confirm that the license covers the whole medical device list 3- DOC acc. to Canadian regulation indicating the classification. 4- The Manufacturer certificate to cover export of medical devices (= Free sale) issued from: The Health Products and Food Branch Inspectorate (HPFBI), Health Canada. 5- ISO 13485:2016.

Third: Technical Documentation

1- Administration

1. Name of manufacturer

2. Address of manufacturer

3. Address of any associated manufacturing sites

4. Statement of legal liability

5. License of manufacturing no. (attachment)

6. Name of the authorized person

7. Authorized person Delegation Letter (attachment)

8. Name of contact person

9. Tel.

10. Fax

11. E-mail

12. Web address

2- Device description

1. Name of the device

2. Brand name

3 Variant: codes, references, and sizes

4. Intended use

5. Description of individual components included in the IVD

Where applicable, the following should also be provided.

6. A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IVD.

7. For assays requiring instrumentation, a description of the relevant instrumentation characteristics or details of dedicated instrumentation to be used.

8. A description of any software to be used.

9. A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.

3- Device History (Transitional State only)

1. A summary of the product history in domestic market and any other countries (attachment)

2. A list of countries or regulatory jurisdictions, approximate numbers of IVDs and/or period of time supplied, summary of any adverse events, recalls, corrective/preventive actions or refusal to approve for supply (attachment)

4- Performance evaluation (as a statement)

- Diagnostic sensitivity

- Diagnostic specificity

5- Labeling

1 Inner and outer labels

2 Instructions for use

3 Advertising material (eg, brochures, web-pages, published advertisements, etc.), where available.

6- Manufacturer testing reports of the final product

Example of batch release certificate

7- Commitment to follow up with PMS medical device.

Appendix V

Check list of IVDs import approval

Acceptance No.	
Applicant name	
Medical device name	
Manufacturer name	
Country of origin	

First: Documents of the import approval applicant:

1. An official request for obtaining an import approval signed and stamped by the responsible manager of the importing company.
2. The authorization of the importing company for the person responsible for dealing with the Central Administration of Medical Devices signed and stamped by the responsible manager of the company along with authentication the signature of the person responsible for dealing with the Central Administration of Medical Devices by the bank (The original shall be submitted for perusal).
3. Submitting evidence of obtaining the user's name & password of the importing company (the e-mail sent by the Quality Department of the Central Administration for Pharmaceutical Affairs).
4. 3 copies of the proforma invoice.
5. Submitting evidence of sending the excel sheet of the invoice items according to the form published by the administration (provided that the excel sheet shall be sent to the e-mail address of the Import Approval Department. (md.invoice@edaegyot.gov.eg).
6. A copy of the importer's registration license (for kits and /or medical devices):

   The supplier / manufacturer company shall be added to the license based on the relationship letter (The original shall be submitted for perusal).
7. Register 14 for agents (The original shall be submitted for perusal).
8. A copy of a valid distribution or agency contract with the supplier company (The authenticated original shall be submitted for perusal).
9. A copy of the relationship document between the manufacturing company and the supplier company (in case that they are not the same company) that stipulate that the supplier company is eligible to supply the devices imported to Egypt or the Middle East issued by the foreign manufacturer, the document shall be authenticated by the Chamber of Commerce and the Egyptian embassy. (The authenticated original shall be submitted for perusal).
10. **In case of the import was for the purpose of Clinical Trial:**

- The approval of the Institutional Committee to Review the Ethics of Medical Researches in the research institution.

(It shall be excluded from submitting quality certificates or registration notifications based on the submitted original protocol).

11. The issue shall be presented to the Import Committee for evaluation in the following cases:

- In case of the importer is a commercial company which supply the devices for a research entity (in case of lack to quality certificates).
- In case of the importer is a research center / entity.
- In case of the importer is a university or researcher which supply the devices for the purpose of scientific research.
- In case of the importer is a hospital which supply the devices for medical purpose / scientific research.

An undertaking shall be submitted by the beneficent entity/ user of the imported devices of not to use them in diagnostic applications, and they shall be used only in the fields for which they were intended (for example: the research or educational field), regardless of the suitability of the devices for the diagnostic uses.

- The device shall be exempted from being presented to the Import Committee if evidence stipulate that the supplied devices are "For Research Use Only" or they are not used for any medical or diagnostic purpose, by submitting the labeling, IFU or the catalog of the manufacturing company.

Second, Free sale certificates and international quality certificates:

1. **Pursuant to the applicable rules of the European community based on the provisions indicated in the "IVD Directive 98/79/EEC":**

Class	Certificates
General IVD **Examples:** * Hematology and clinical chemistry analyzers * Tests for hormones * Cardiac markers * Hematology and clinical chemistry tests	1. DOC certificate indicating IVD Directive and classification. 2. "FSC" certificate issued by the origin country or by one of the reference countries. 3. A Catalog showing the purpose of use.
IVDs for self -testing: **Examples:** * Pregnancy, cholesterol home test * self-testing devices	1. DOC certificate indicating IVD Directive and classification. 2. "FSC" certificate issued by the origin country or by one of the reference countries. 3. ISO Certificate13485 :2016. 4. CE III certificate CE IV certificate, CE V+VI certificate or CE V+VII certificate. 5. A catalog showing the purpose of use.
IVDs in Annex II List B (Moderate risk) Examples: Rubella, PSA, Self-Test for Blood Glucose (monitoring system or strips)	1. DOC certificate indicating IVD Directive and classification. 2. "FSC" circulation certificate issued by the origin country or by one of the reference countries. 3. ISO certificate13485 :2016. 4. CE IV certificate, CE V+VI certificate or CE V+VII certificate 5. A catalog showing the purpose of use.

IVDs in Annex II **List A** **(High risk)** Examples: HIV, Hepatitis, ABO Blood Grouping	1. DOC certificate indicating IVD Directive and classification. 2. "FSC" certificate issued by the origin country or by one of the reference countries. 3. ISO certificate 13485 :2016. 4. CE IV certificat, or CE V+VII certificate 5. A catalog showing the purpose of use.

2. Pursuant to the applicable rules in the USA based on the provisions indicated in FDA

Class	Certificates
Class I	1. CFG certificate without GMP. 2. Letter of declaration certificate indicating the classification. 3. Code of federal regulation: 21CFR 862, 21CFR 864 or 21CFR 866 4. A catalog showing the purpose of use.
Class II, and III	1. CFG certificate with GMP, or CFG + ISO13485:2016 certificates 2. Letter of declaration certificate indicating the classification. 3. Code of federal regulation: 21CFR 862, 21CFR 864 or 21CFR 866 4. A catalog showing the purpose of use.

3. Pursuant to the applicable rules in Canada:

Class	Current status
Class 1	1- DOC acc. to Canadian regulation indicate the classification 2- Manufacturer certificate to cover export of medical devices (= FSC) issued from: the HPFBI, Health Canada 3- Medical device establishment license 4- A catalog showing the purpose of use.
Class II, III, IV	1- A valid license of the medical device (In case of valid license of the medical device, it shall be issued for the medical device family, medical device group or medical device group family). **N.B**: The declaration letter shall be sent to the health Canada to confirm that the license covers the whole medical device list. 2- Declaration of conformity acc. to Canadian regulation indicating the classification. 3- Manufacturer certificate to cover export of medical devices (= free sale) issued from: the HPFBI, Health Canada. 4- ISO 13485:2016. 5- A catalog showing the purpose of use.

Appendix VI

The necessary Requirements for In Vitro Diagnostic Medical Devices Manufacturers

1-Facilities & Utilities	based on product properties
Workers Entry Area	
1. The toilets shall be separated from the gowning area, provided that the toilets shall be located before the gowning area. 2. A shoe stand (open stand) shall be provided for street shoes and another one for toilet shoes. 3. A source of ventilation shall be provided in the toilets. 4. Air curtains and insect repellents shall be installed at all entrances to the factory that locate on the street.	
Gowning area: It is the area in which the street clothes are replaced with factory clothes. It is an unclassified area.	
1. The shoes worn in the street shall be separated from those worn inside the manufacturer. 2. De-gowning area should be separated from gowning one. 3. A source of ventilation shall be provided with a ventilator fan to draw air outside and supply fresh air to the area. 4. Step over bench lockers shall be provided – made from coated metal or stainless steel. 5. There should be a gowning area for women and another one for men. 6. A locker should be provided to street wear and another one to the factory wear. 7. It is prohibited to provide the gowning area with water source. 8. Disinfectant shall be provided for purifying the hands. 9. Walls and floors shall be solid with smooth surfaces and without visible joints. In the case of existing joints (expansion joints), they shall be treated according to industrial codes so that they shall not contain any dust or particles and they shall be on the same degree of softness as the floors. 10. The area shall be good ventilated. 11. The area shall be good lighted and not covered. 12. Any ventilation opening shall be covered with a mesh wire with narrow openings to protect the area against flying insects or the like.	
Production area	
Controlled Area: It is the area in which the products, that do not require to be produced in a clean room, are manufactured and packaged.	
1. It shall be a separated area and shall not be used as a corridor. 2. An adequate source of ventilation shall be provided. 3. The temperature shall not exceed 30°C and the humidity shall not exceed 65%. 4. The specific requirements of each product regarding temperature and humidity shall be met in accordance with the product data and specifications certificate and / or in accordance with the MSDS. 5. For the in vitro medical device which their production requires reducing humidity rate, a dehumidifier or one of the other engineering methods shall be provided to achieve to the required humidity.	

6. The temperatures and humidity shall be measured and recorded periodically in a record designated for this purpose which the environmental conditions of operations can be followed up and referring to it if necessary. 7. Temperature and humidity gauges and any gauges attached to the equipment or production machines whose accuracy is considered in affecting the safety of the desired product, shall be calibrated. 8. The floor shall be smooth, clean and solid. It is preferable to treat the floor surfaces with epoxy. 9. A place attached to the controlled room shall be allocated to store stamps when needed. 10. In case of it is necessary for an intermediate product to move from the Controlled room to the clean room, the following procedures shall be committed: • The product shall be packaged in a double bag. • The product shall pass through dynamic pass box / classified air lock. • The product shall be stored in an intermediate store that complies with Good Storage Practices. 11. The manufacturing phase shall be separated from the packaging phase.	
Clean room: It is the area in which the products, that require to be manufactured and packaged in a classified clean room, are produced	Not applied to products that are not produced and packaged in a clean room
1. It shall be preceded by a secondary gowning area. 2. de- gowning area / then step over bench / then wear secondary gowning. 3. Doors shall be interlocked. 4. Secondary gowning area shall be classified as clean room class D / ISO. 5. An SOP shall be hanged explaining to the workers the procedures of entrance of the clean room. 6. Calibrated gauges shall be installed to measure the pressure difference between chambers in a standard range from 0 to 60 Pascal. 7. The gauges readings shall be recorded and reviewed periodically. 8. It shall be ensured that the pressure difference between the chambers ranges between (5-10) Pascal. 9. The opening direction of the doors shall be to up (more positive). 10. The floors and walls shall be smooth and the walls shall meet with the ceiling or floors in a circular or semi-circular shape (curved). 11. The temperature should not exceed 22 +/- 2 °C and humidity 65 +/- 5%, unless there are specific technical requirements for the product. 12. In the case of printing on the product, the printing shall be carried out inside the clean room, and in the case of using inks, physical separation shall be carried out. 13. The raw materials shall be entered through a dynamic pass box / classified air lock. 14. The supply grills should be in the ceiling and the return grills in the side walls and its high should be 50 cm above ground level. 15. The height between ceiling and floors shall not be less than 2.6 meters. 16. The air change rate shall be in accordance with class D: Number of air changes from 15 to 20 changes per hour according to ISO standard 14644 17. Standard Operating Procedures should be hanged, explaining in details the steps for entering the clean room.	

Stores Stores shall be divided into the following areas: raw material storage area / packaging storage area / rejected products area which shall be sealed and secured / finished product storage area / storage area for any raw materials or products that require special storage conditions.	
1. They shall be well ventilated. 2. The Storage requirements for products / raw materials shall be fulfilled. 3. The temperature and humidity shall be monitored by Data Loggers and Thermal Mapping. 4. The floors shall be solid. 5. A rodent control system shall be applied. 6. All store doors shall be tightly closed against the dust and insects 7. Any ventilation opening shall be covered with a mesh wire with narrow openings. The glass windows shall be treated (tinted) to prevent direct sunlight from entering. 8. Adequate lighting shall be provided. 9. It is prohibited to provide the storing area with a direct water source. 10. It is prohibited to store directly on the ground. The store shall be on non-combustible pallets / stands and they shall be 60 cm below the ceiling and 20 cm from the walls. 11. The store area shall be suitable to the production capacity of the manufacturer. 12. If a refrigerator is required, the following procedures shall be committed: • It shall have calibrated thermometers. • The temperatures shall be read and recorded periodically.	

Lab	
a. Individuals • The factory quality control manager shall have the necessary professional qualifications and competence in terms of academic qualification (science / pharmacy / veterinary medicine / human medicine) in addition to five years of experience in the same field. • All workers associated with the lab and affecting its activities shall be qualified and impartial in accordance with the management system. • Competence and training requirements for all employees shall be documented (competence file). • Each person has a role affecting the lab activities, shall have the education, qualification, training, technical knowledge, skills and experience. • It shall be ensured that the staff are competent in performing the lab activities for which they are responsible and the amount of deviation in their assignments shall be evaluated.	
b. Equipment • All equipment required to perform the tests shall be available in accordance with the requirements of the product. • The requirements of the Standard shall be fulfilled for all equipment used in the lab. • The equipment necessary to determine metrological traceability should be calibrated when the measurement accuracy or measurement uncertainty affects the validity of results. • The calibration program shall be adhered to. • The equipment shall have labels indicating the status of the equipment in relation to calibration.	

• The out-of-service equipment shall be isolated and shall not reused until their proper working are verified.	
c. Records • The equipment affecting the lab activity shall have records, which include: o Calibration dates and results, adjustments results and acceptance criteria. o The due date of next calibration or interval of calibrations. o Maintenance plan and maintenance performance. o Details of damage, malfunction, modification or repair. • The IPC process and procedures shall be documented as well as the records of results. • The lab shall fulfill the technical specifications of the product(s) and raw materials. d. In case of manufacturing sterile products and / or manufacturing a product which at any stage required to be in a classified clean room, microbiology laboratories shall be available with all the necessary equipment to perform the required tests. e. In case of lacking to a quality control lab in the factory, the factory shall be obligated to contract with a previously licensed external lab and it shall subject to the inspection in order to ensure that all the necessary requirements for conducting tests on the factory's products are fulfilled. f. The contract shall include a clause that allows inspection of the lab with regard to the analysis of the products subject to the contract. Under this clause, as well as, the lab shall be obligated to provide the records of the evaluation and analysis of these products.	
Generator	
1. In case of there are special requirements for manufacturing or storing the product, a generator connected to the electrical circuit of the factory shall be provided. 2. The devices and equipment that operate by the city's electricity grid and the generator shall be specified in a clear engineering lay out to be submitted upon request. 3. It is preferable to provide uninterrupted power supply UPS.	
Heating, ventilation, and air conditioning (HVAC) system	Not applied to the products that are not produced and packaged in a clean room
1. The Air Handling Unit shall include the following: Prefilter/ Bag Filter / HEPA filter. 2. A gauge to measure the pressure difference shall be installed at the prefilter and the Bag filter, as well as a gauge to measure the pressure difference shall be installed before and after the HEPA filter. 3. The HVAC unit shall be covered by a canopy, the floors shall be tiled and the surrounding area shall be kept clean. 4. The maintenance and filter change process shall be documented. 5. The necessary tests shall be carried out to ensure the safety of the HVAC unit and its compliance with the requirements.	
Water system **1. Water station**	Not applied to the products that do not use treated water in the manufacturing process
1. In case of using water in the manufacturing process, the factory shall have a water station that meets the necessary requirements for water production in accordance with the technical requirements stipulated in the technical specification of the product or the water specifications for lab use stipulated in the latest versions of ASTM.	

2. The water station can be minimized Reverse Osmosis (RO) devices without softeners before it, in the case of small quantities of 100 liters per day. In case of the factory needs more than this quantity, a water station shall be provided that includes: sand filter, micron filters, softener, carbon filter or sodium metabisulfite injection system and the RO unit, then another stage of the RO if the specifications require that. 3. In the case of using water directly without storage, small RO devices or a water treatment plant according to production needs can be relied upon. 4. In case of the water is used in quantities that need to be stored in the production processes, this storage shall be through a closed path (stainless steel 304 pipes at a minimum) (the entry and exit of which shall be through this closed loop). 5. The factory shall conduct and document the water tests to ensure that they comply with the requirements. 6. In the case of outsourcing of water, the factory shall fulfill the requirements stipulated in the material control item.	
2. **Material control**	
A. An approved supplier list shall be available. B. A list of supplier selection check list shall be available. C. The selection criteria shall include criteria related to quality, safety and performance.	
3. Production / process control	
Verification of critical processes	1. The factory shall determine the most critical processes / steps based on the standard specification of the product and the manufacturing steps that are performed in the factory. 2. The factory shall set documented procedures for the verification of critical processes. 3. The factory shall keep records of verification studies.
Traceability & Identification	1. The factory shall set a system for identify and determine the product identity. 2. A documented procedure shall be set to identify and explain this system. 3. The factory shall set a documented procedure to explain the mechanism of the product traceability.
Competence & Training	1. The manufacturer shall determine the standards of competence required in the persons responsible and in charge of the work that affect the quality of the product. 2. The manufacturer shall provide the required training and / or take other measures to fulfill these requirements. 3. The manufacturer shall evaluate the effectiveness of the measures taken. 4. The manufacturer shall ensure that the employees understand and realize their roles and contributions in achieving the quality objectives. 5. The manufacturer shall document all the previous steps. 6. The records of the training, skills and experience of workers shall be kept.
Non-conformities	1. The manufacturer shall ensure that the non-conforming product is well defined and under control to prevent wrong and unintended circulation. 2. The manufacturer shall set a documented procedure defining the responsibilities and authorities for dealing with cases of non-conforming products. 3. The manufacturer shall set and keep records of the non-conforming products specifying the nature or cause of the non-conformity and the measures taken in respect thereof. 4. In case of detecting a non-conforming product after the product has been circulated in the local market, the manufacturer shall take all the necessary measures that commensurate with the potential effects of the non-conformity.
4. **Record / document control**	

General requirements: The processes required for the quality management system should include (management activities, providing of resources and product realization and measurement).	
1. The manufacturer shall set, document, implement, maintain a quality management system and maintain its effectiveness in accordance with the requirements of the international standard ISO 13485. 2. The manufacturer shall define the necessary processes for the quality management system and shall apply them throughout the factory. 3. The manufacturer shall determine the sequence and interaction of these processes. 4. The manufacturer shall determine the necessary standards and methods to ensure the effectiveness of operating and controlling these processes. 5. The manufacturer shall ensure the availability of the necessary resources and information to support the operation and control of these processes. 6. The manufacturer shall monitor, measure and analyze these processes. 7. The manufacturer shall implement the actions necessary to achieve the planned results and maintain the effectiveness of these processes. 8. The manufacturer shall manage these processes in accordance with the requirements of this International Standard. 9. These processes shall be under control within the quality management system when outsourcing to external sources.	
Documentation requirement	
1. General	1. The quality management system documents should include the following: - Documented statements of quality policy and quality objectives. - Quality Manual. - Documented procedures required by this International Standard. - The documents required by the organization to ensure the effective planning, operation and control of its operations. - Records required by the international standard. - Any other documents specified by the national or regional regulations. 2. The factory shall set and maintain a file for each type of products. The file either contains or specifies documents determining product specifications and quality management system requirements. 3. These documents shall specify the complete manufacturing process, installation and maintenance, if any. 4. Documentation may be in any form or type of media.
2. Quality manual: The quality manual defines the documentation structure used in the quality management system	The manufacturer shall set and maintain a Quality Manual which includes the following: - The quality management system, including the details and justification for any exclusions and / or non-conformities. - The documented procedures set for the quality management system that may referred to.

	- Describing the interaction between the processes of the quality management system.
3. Control of document	A documented procedure shall be set to determine the necessary controls to: - Review and approve the appropriate documents prior to issuance. - Review, update and re-approve documents when necessary. - Ensure that the changes are identified and the current revision status of documents also identified - Ensure of accessibility of the relevant versions of the applied documents at the points of use. - Ensure that the documents remain legible and easily identifiable. - Ensure that the documents of external origin are identified and their distribution are monitored. - Prevent unintended use of the outdated documents and apply a proper identification to them if they are retained for any purpose.
4. Control of records: The entity shall maintain records for a period of time not less than the life of the product as specified by the manufacturer and for at least two years from the date in which the product was produced by the relevant manufacturer or as specified by the regulatory requirements.	1. Records shall be set and maintained to provide evidences of conformity and effective operation of the quality management system. 2. Records shall remain legible and can be easily identifiable and retrievable. 3. Documented procedures shall be set to define the controls necessary for records identification, storage, protection, retrieval, retention period and records disposal.
Organization chart	
1. An organizational structure for the factory shall be established. 2. The roles and responsibilities for all positions shall be identified. 3. Quality Management shall be an independent department to ensure that their decisions enjoy freedom and integrity.	

Appendix VII

Application for re-reg of IVD

Type of application: Local / imported	
Current registration number:	
Registration date:	
Applicant name:	
Applicant Address:	
Applicant Email address:	
Applicant telephone:	
Trade name:	
Description:	
Variant: codes, references or kit sizes:	
The intended use / indications:	
Legal manufacturer name:	
Manufacturing site name: multiple	
Manufacturing site address:	
Country of origin: multiple	
List of changes from the registered IVD:	

Appendix VIII

Safety Requirements

First: vigilance requirements for in vitro diagnostic medical devices:

General, Self – Testing IVDs ** no control procedures were taken

The companies shall be obligated to submit an undertaking which shall be sent by the legal manufacturer to the Administration of IVD Listing in the Central Administration of Medical Devices directly via the registered mail and not through an agent. The transfer letter shall not be issued for them to address the Vigilance Department.

All List A, B IVDs, and General, Self- Testing IVDs had control procedures in the three (3) years prior to the date of submission.

- The companies shall be obligated to address the Vigilance Department, under the transfer letter issued by the Administration of IVD Listing in the Central Administration of Medical Devices, to submit the documents required to evaluate the safety in the framework of registration / re-registration / making variables (which includes a summary of the marketing history).
- The required undertaking shall be submitted (attached herein) to Administration of IVD Listing in the Central Administration of Medical Devices directly via the registered mail not via an agent, provided that it shall be sent by the legal manufacturer.

Second: Vigilance requirements for companies (not related to registration):

1. The companies shall be obligated to provide the applicant's vigilance system.
2. The companies shall be obligated to appoint a vigilance responsible to the applicant or to add his duties to the supervisory affairs officer, and submit his nomination letter to the Vigilance Department.
3. The companies shall be obligated to pay for services when submitting their files to the Safety Department.
4. The companies shall be committed to apply any developments regarding safety requirements (if any).

[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 / re-registration / 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 IVD 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**:**

- **IVDs 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 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 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

6. Glossary

ASTM: American Association for Testing and Measurement
CE: Conformity European
CFG: Certificate to Foreign Government
CFR: Code of Federal Regulation
DOC: Declaration of conformity
EDA: Egyptian Drug Authority
EEC: European Economic Community
EPVC: Egyptian Pharmaceutical Vigilance Center
FDA: Food and Drug Administration
FSC: Free Sale Certificate
FSCA: Field Safety Corrective Actions
FSNs: Effective Field Safety Notices
GHTF: Global Harmonization Task Force
GMP: Good Manufacturing Practice
GSP: Good Storage Practice
HEPA Filter: High-efficiency Particulate Air Filter
HIV: Human Immunodeficiency Virus
HPFBI: Health Products and Food Branch Inspectorate
HVAC System: Heating, Ventilating, and Air Conditioning System
ISO: International Organization for Standardization
IVDs: In vitro Diagnostic Medical Devices
IVDR: In vitro Diagnostic Device Regulation
MDSD: Medical Device Safety Department
MIRs: Manufacturer Incident Reports
MSDS: Material Safety Data Sheets
PMS: Post-Market Surveillance
PSA: Prostate Specific Antigen
PSRs: Periodic Summary Reports
RO: Reverse Osmosis
ROC: Receiver Operator characteristic
SMH: Summary of Marketing History
SOP: Standard Operating Procedure