Regulatory Guideline for

Procedures of Registering Imported and Local Medical Devices holding International Quality Certificates

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1. Introduction

This guideline is concerned with the regulatory procedures of registering imported and local medical devices that have international quality certificates.

2. Definitions:

Medical Devices: Any instrument, apparatus, appliance, tool, application software, implant, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- devices for the control or support of conception
- products specifically intended for the cleaning, disinfection or sterilization of devices
- Provided that it does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Imported Medical Devices: Devices which are completely manufactured abroad and imported to be sold and placed on the market within the Arab Republic of Egypt.

Locally manufactured Medical Devices: Devices which are manufactured in sites/facilities inside the Arab Republic of Egypt.

Registration applicant: It refers to an importing company, local facility or scientific office.

Representative of the registration applicant: He is the representative delegated by the registration applicant to follow up all the works within the Department of Registration.

A Non-sterile Medical Device: It is the medical device that is not subject to sterilization process after manufacturing and used in its non-sterile state or require to be sterilized by the user before use.

Importing company: It is the first entity in the supply chain that imports medical devices manufactured abroad into the Arab Republic of Egypt.

Normal Track Registration System: It is the pathway through which the the review for a variation in a registered medical device license is conducted according to the waiting list of the administration of medical device variations.

Fast Track Registration System: It is the pathway through which the review for a variation in a registered medical device license takes priority without being bound by the waiting list of the. administration of medical device variations.

F-Toll Manufacturing:

*** Factory: It is the actual manufacturer of the medical device, which:**

- **is licensed by the competent authority in accordance with applied rules.**
- **holds CE & ISO 13485:** 2016 certificates issued by an internationally accredited certification body.
- **The availability of a production line in the factory license**

- **Registration License Holder or "License Holder**": It is the factory applying for registration of a medical device which will be manufactured by another factory which is:

- **A licensed factory in accordance with applied rules (factory of medical devices or medicine).**
- **A factory that holds CE & ISO 13485**: 2016 certificates issued by an internationally accredited certification body that covers the actual place of manufacturing.
- **A factory that is legally responsible for the medical device.**
- **A factory that, at the present time, does not have a production line for the medical device for which a registration application has been submitted, or that has the production line but its production capacity is less than actually required production.**

- **Legal manufacturer:** It is the entity responsible for designing, manufacturing, packaging and labeling the medical device before placing it on the market under its own name, regardless of whether these operations were carried out by this entity himself or on his behalf or by a third party. The legal manufacturer shall be responsible for the quality of the product.
- **Actual manufacturer:** It is the entity where the medical device is in fact manufactured, and packed on behalf of the legal manufacturer

List of Reference Countries:

Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom and United States of America

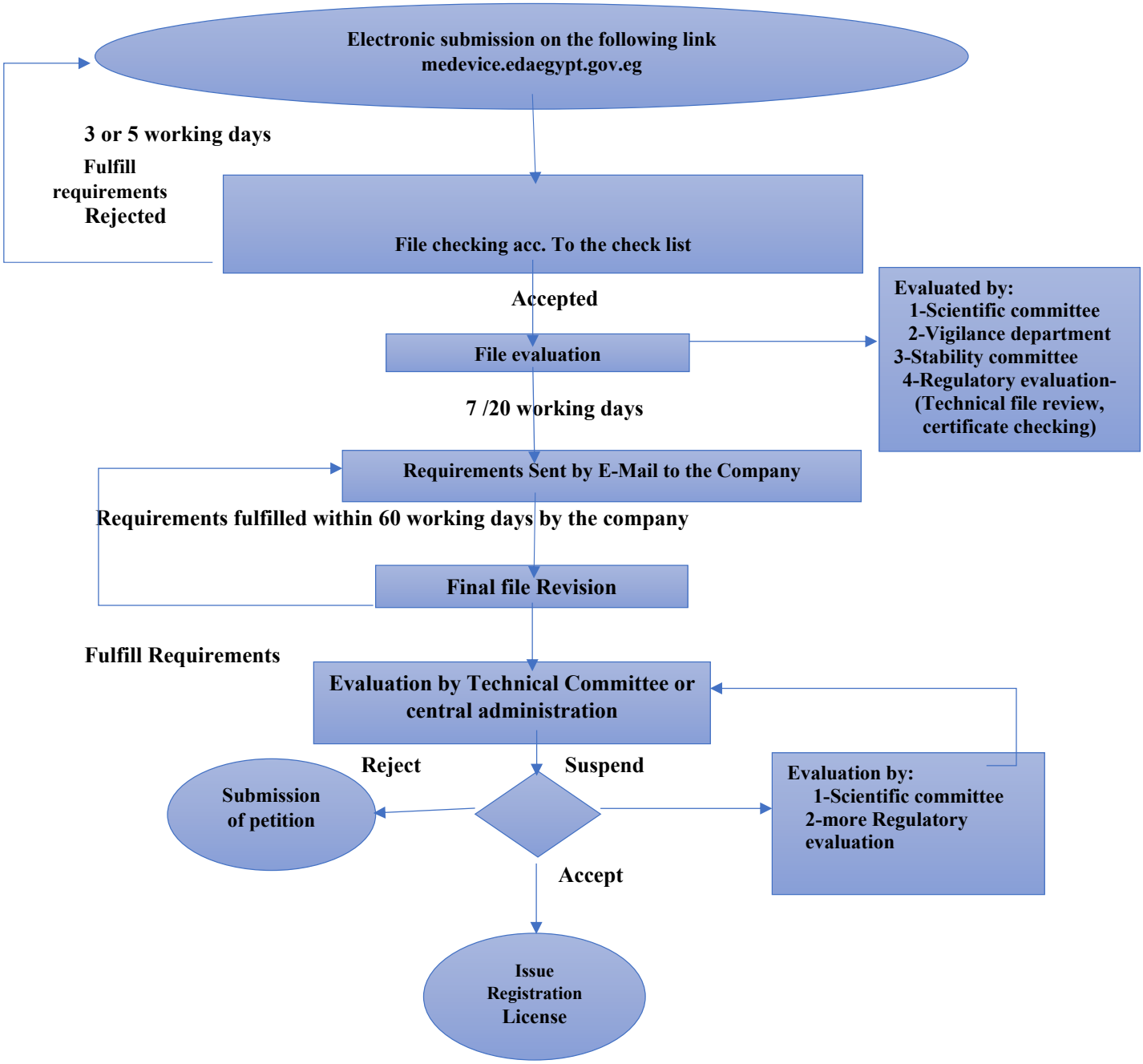
3. Relevant Regulatory Guidelines:

- Guideline of technical requirements for medical devices' factories
- Regulatory Guideline for the Regulating Procedures for Registering Imported and Local Medical Devices that Have International Quality Certificates.
- Regulatory Guidelines for the Medical Device Vigilance System.

4. Regulatory Procedures and Rules

4.1 Procedures and rules regulating the registration of sterile imported and local medical devices that have international quality certificates.

Flow Chart (1) of Registration of Medical Devices



4.1.1 Procedures of receiving medical devices registration files:

1. A pharmacist from evaluation and assessment administration meets the registration applicant's representative to add the name of the medical device on the payment receipt of the fees and to specify the concerned department (local - imported).

The fees of a medical device registration application shall be collected as per the fee category contained in the executive regulations of the law of establishing the Egyptian Drug Authority "promulgated by Prime Minister's Resolution No. 777 of 2020" and the service fees shall be collected as per the decree issued by the Chairman of the Egyptian Drug Authority in this regard.

2. The company should apply on the electronic platform at the following link:

medevice.edaegypt.gov.eg

3. The company will receive a response through the platform within 5 working days from the date of submitting a normal track request and 3 working days for the fast-track request with acceptance/rejection/or suspending the request until meeting the requirements

- If the file is accepted: the request is directed to the reviewer pharmacist and the unit head for studying, reporting and sending the requirements for the company for completion
- In case of suspension of the request until meeting the requirements: the file is suspended if any of the documents does not meet the requirements according to the published checklist for a period of 90 working days at most, after which the request shall be considered as cancelled

When the company meets the necessary requirements, the request will be completed on the platform with the same request number previously acquired

- **In case of refusing the application: In case of Rejection of the request: the** request is rejected if any of the device's data in the company's request mismatch with the payment receipt or the required documents or if the request does not concern the addressed department.

4.1.2 Procedures of evaluating a medical device's registration file

- The file is reviewed and requirements are sent on the platform within 20 working days from the date of accepting a normal track file and 7 working days for fast-track files
- Procedures of medical devices safety shall be adhered to as it is mentioned in detail in Section 8.

4.1.3 Procedures of completing a medical device's registration file

- Fulfilled documents required for the registration file shall be sent through the platform medevice.edaegypt.gov.eg.

The following items shall be adhered to regarding documents uploaded on the electronic platform by the companies:

- Documents must be original.
- Documents must be stamped with **the company's official stamp.**
- Documents must be **Signed by its legal representative.**
- Documents may be sent either **through scanning and uploading them or using an electronic signature**

Note: Other electronic documents shall not be accepted.

4.2 Procedures and rules regulating the registration of non-sterile imported and local medical devices that have international quality certificates.

4.2.1 Procedures of registering non-sterile imported medical devices classified as Class IIa, IIb, III.

In case a complete registration file is available in accordance with the checklist (Appendix 1).

The same steps and rules mentioned in paragraph 4.1 shall be followed as shown in workflow no.1.

In case only an initial registration file is available

, which means a complete registration file is not available in accordance with the checklist (Appendix 1).

The following procedures shall be followed as shown in workflow no. 2

The registration applicant shall, in parallel, submit an initial registration file on the following link: md.nonsterilereg@edaegypt.gov.eg, which contains a copy of the certificates submitted to the General Administration of trading allowance for each medical device.

The following documents are sufficient for the initial registration file:

- Declaration of conformity
- CE certificate
- ISO 13485:2016
- Free sale certificate from a reference country in case of devices classified as Class II b, III.
- Free sale certificate from the country of origin in case of devices classified as Class II a.

*** In the initial registration file:**

- For devices classified as Class IIa: It is sufficient to submit a free sale certificate from a non-reference country in case a free sale certificate is not available from one of the reference countries, provided that a free sale certificate from one of the reference countries shall be submitted within the grace period of (6 months).
- In case the_ISO 13485:2016 certificate is not available for all medical devices with various classifications, the file shall be received temporarily, provided that it shall be submitted within the grace period of six months.
- In case any of the items mentioned in the invoice submitted in the application for obtaining an importing approval is considered as a part of a group of non-sterile devices, a registration file of all the items of the group shall be submitted in the same initial registration file.

Action Steps:

1. Temporary acceptance numbers shall be granted by the Registration Department based on the submitted request and the attached certificates.
2. An importation approval will be issued after obtaining the temporary acceptance number through the Registration Department.
3. Companies shall be granted a period of 18 months from the date of accepting the initial registration file so that they complete the remainder of the registration file, provided that the first six months shall be devoted to complete the main documents of the registration file in accordance with Appendix 1.

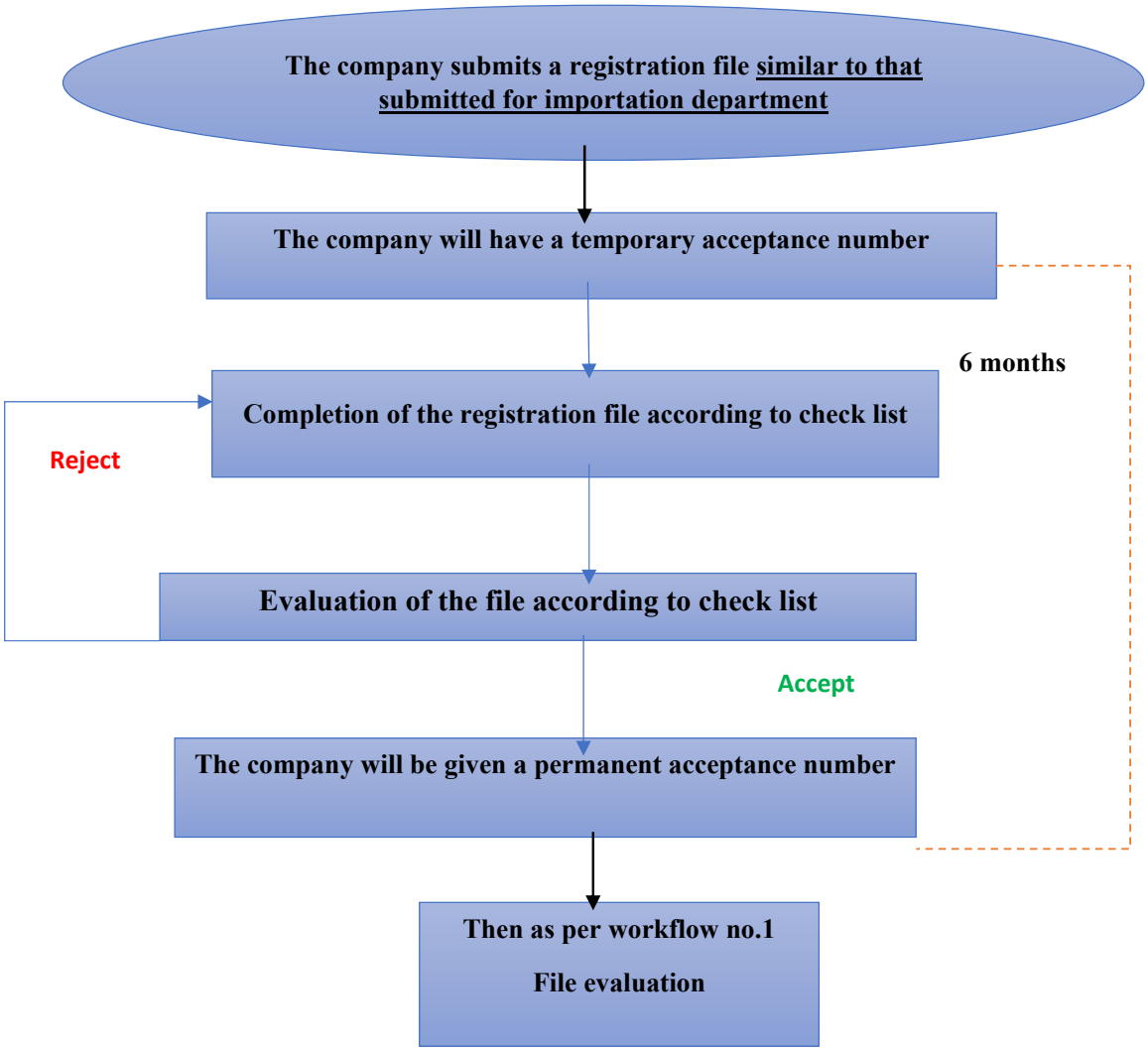
- During the first 6 months, the company shall submit the registration file in accordance with Appendix 1 at the following link: medevice.edaegypt.gov.eg
- The company shall then be given a final acceptance number, will be granted a one-year grace period for importation until the registration procedures are completed, as followed in item 4.1.

4-The consent/approval of issuing any importing approval will not be provided after the expiry of the previously mentioned period without completing the required documents in accordance with the checklist (Appendix 1).

NB:

- In case of repeated importation of the same item submitted for registration in more than one importing approval, the company shall use the same temporary acceptance number without being referred to the Registration Department to prove this.
- The registration applicant is permitted to submit an initial registration file without being required to apply for an importing approval.

Flow Chart (2) of Registration for Medical Devices Class IIa, IIb, III



4.2.2 non-sterile local medical devices classified as class IIa, IIb, III

Factories will be given a period of two years for reconciliation of their situations from the date of the issuance of the guideline to complete registration procedures.

- During the period of reconciling their situations, trading will be under the responsibility of the factories, as the situation/practice before the issuance of the guideline.
- provided that an initial registration file must be submitted during the first 6 month,
  The following documents are sufficient for the initial registration file:
- Declaration of conformity
- CE certificate
- ISO 13485:2016
- Free sale certificate from a reference country (if available).

Action Steps:

1- Temporary acceptance numbers shall be granted by the Registration Department based on the submitted request and the attached certificates.

2- Companies shall be granted a period of 18 months from the date of accepting the initial registration file so that they complete the remainder of the registration file, provided that the first six months shall be devoted to complete the main documents of the registration file in accordance with Appendix 2.

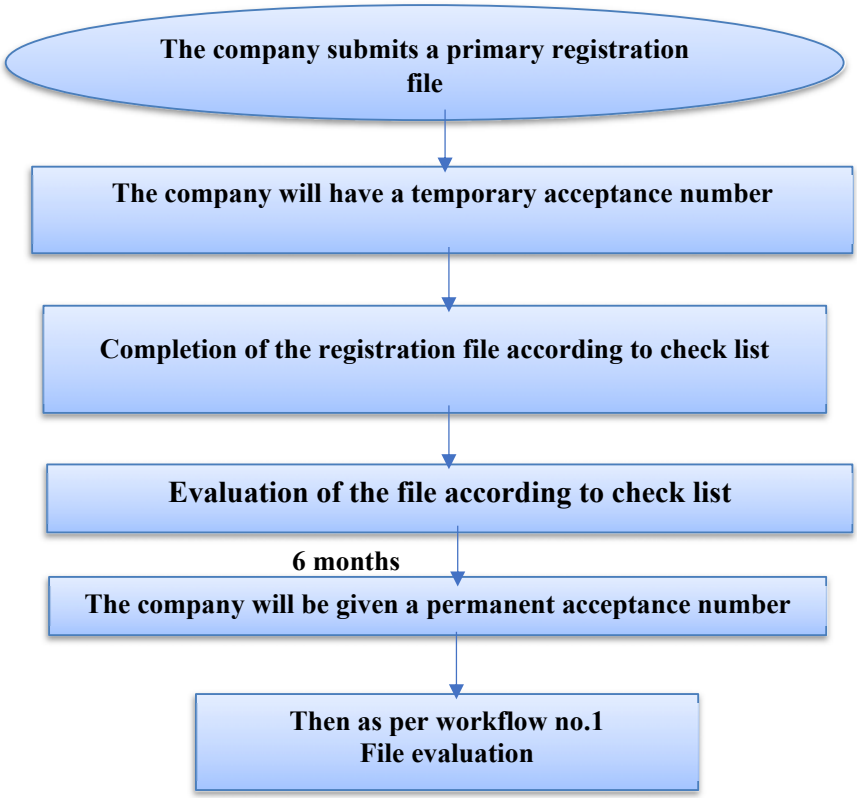
- During the first 6 months, the company shall submit the registration file in accordance with Appendix 2 at the following link:

medevice.edaegypt.gov.eg

- The company shall then be given a final acceptance number, and will be granted a one-year grace period for importation until the registration procedures are completed, as followed in item 4.1.

No permission shall be given for importing production raw materials, components and inputs after the end of the granted period.

Flow Chart (3) of Registration for Medical Devices Class IIa, IIb, III



4.2.3 Registering non-sterile medical devices as a system:

A group of non-sterile medical devices must be considered as a system and be registered with a single registration number in the following cases:

A. The non-sterile medical devices must have the same legal manufacturer.
B. One of the certificates (free sale, CE certificate, CFG certificate from USFDA, declaration of conformity) must state that the provided medical devices are a system.
C. presentation to the specialized scientific committee to ensure that all items work complementary to one another to form a system.

It is not required that the non-sterile medical devices share the following:

raw material-GMDN-patient population.

4.2.4 Registering non-sterile medical devices using the bundling system

The bundling system can be applied to the registration of the non-sterile medical devices in case that the devices share the following:

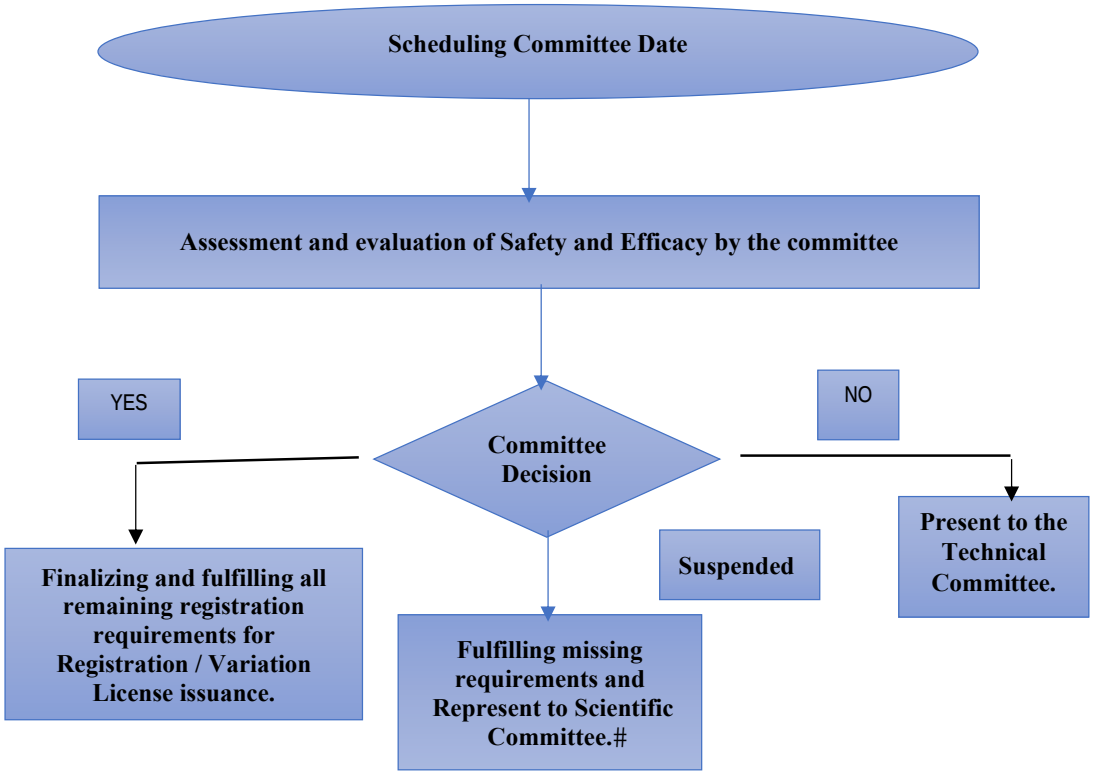
A. Same legal manufacturer
B. Same classification.
C. Same generic proprietary name.
D. Common intended use.
E. Similar or close design.
F. Be within scope of the permissible variants that may be evaluated by scientific committee.

It is not required that the non-sterile medical devices share the following:

raw material- GMDN-patient population.

5. Procedures and rules regulating specialized scientific committees

Flow Chart (4) of Scientific Committee for Medical Devices



Scientific committees are divided into different specializations and presentation to one of them is held based on the purpose of use of the medical device or equipment to be presented.

Devices that are subjected to specialized scientific committees' evaluation as a step prior to registration are:

- Devices submitted for new registration or re-registration, which are imported from non-reference countries or locally manufactured.
- Devices submitted for new registration or re-registration, presented to the committee for it to express its opinion on whether the differences between the medical devices are substantial so the medical devices should be registered separately or not.
- Medical devices in a dosage form to evaluate the following points:

- Safety & effectiveness

- OTC or Prescription

Claims on label and intended use in IFU

- Devices submitted for new registration or re-registration, which their safety reports issued by the medical device's safety unit recommend the presentation to the scientific committee to evaluate and express their opinion on the safety report or the evaluation of their reports issued by the medical device's safety unit requires the presentation to the scientific committee.
- Medical devices presented to the scientific committee to clarify some technical points.

Action Steps:

- Transferring the topics that require the presentation to the specialized committee of medical devices registration / the Central Administration of Medical Devices to take the necessary action.
- Convening the committee and presenting the topics in addition to the samples to the members for study and expressing the scientific opinion.
- Issuing the final decisions on each topic presented (approval/reasoned reasonable suspension/ reasonable rejection).
- In case of suspension, the requirements shall be fulfilled through the platform medevice.edaegypt.gov.eg, then the topic will be re-presented to the scientific committee.

*** The following should be taken into account for the following medical devices:**

Medical device name / category	Prerequisites
Anesthesia	
Infusion, I.V. Set &Administration Set	-Must have safety rubber, Injection Port or Latex. -Must have a needle. Can be with or without vent - Must be not less than 110 cm in length. - The package must have a place designated for easy opening.
Infusion Sets with Burette	Infusion set with burette must contain safety rubber
CVC (Central Venous Catheter not peripheral / central Line Catheter / Infusion Catheter)	- Need to have guiding syringe (guiding Y-connector) (a passage or a side hole in the needle for guide wire entrance-perforated syringe- double injection needle)
Suction catheters	- Need to be without any side holes so as not to obstruct suction procedure.
I.V Cannula	- Must have side pore (injection port) for drug injection unless for sizes 24 and 26 as they are used for neonates and children. - Sample from each cannula size has to be presented to the scientific committee.
Extension Lines	- Have to state whether Venous or Arterial
Breathing Circuit, Oxygen Mask &Nebulizer	- Can be Sterile or Non-Sterile but has to be stated on packaging.
disposable anesthesia breathings circuits	The disposable anesthesia breathings circuits must include all the necessary parts for their use in the following: * In case of the y circuit, the following parts must be present: (Water trap + breathing bag + 3rd limb + CO2 extension) * In case of the co axial circuit, the following parts must be present: (Breathing bag+3rd limb+CO2 extension) must be present in one package for the following reasons: - To avoid connection/reconnection risks - to avoid reuse of part
Endotracheal	- Accept CUFFED for all sizes. - Accept UNCUFFED only for sizes up to and including 5mm. (e.g. 3, 4 & 5 mm which are used for pediatrics). - The Cuffed & Uncuffed Tracheostomy Tubes shall be presented to the Ear, Nose and Throat Committee for specialization.

Endocrinology	
Insulin Pen Needles	The outer label of the pen needles, which mentions all types of compatible pens that can be used with it, must be presented to the scientific committee, based on ISO 11608-2: 2012, which requires that the names of pens that are used with the needles shall be added to the labels.
Insulin syringes	Registration of insulin syringe will not be accepted EXCEPT the 1ml (100 I.U)
Ear Nose & Throat (E.N.T.)	
Tracheostomy Tubes	Cuffed & Uncuffed Tracheostomy Tubes shall be presented to the Committee of Ear, Nose and Throat not the anesthesia.
	Registration of uncuffed & cuffed tracheostomy tubes of all sizes shall be accepted for the purposes of their use in ear, nose and throat surgeries, which are completely different from their use by intensive care physicians.
Ear products class I non sterile	Inquiry requests shall be submitted by the importing companies, including the following: - Soft and hard copy of: Trade name, Class, Product category, Manufacturer name, country of origin, Intended Use, Composition, Mechanism of action, packaging, labeling and instructions for use The following procedure will be implemented: - Presentation to the pharmacology committee to evaluate whether or not. The product has a pharmacological effect In case the product has no pharmacological effect, it is presented to the specialized scientific committee of Ear, Nose and Throat diseases and surgery to evaluate it Considering it is in a dosage form And receiving the registration file of the device is permitted in case of the approval by the scientific committee/scientific committee approval and the notification of the specialized committee of medical devices registration In case the product has a pharmacological effect, it is presented to the specialized committee of medical devices registration.

Nasal dosage form class I non sterile	Inquiry requests shall be submitted by the importing companies, including the following: - Soft and hard copy of: Trade name, Class, Product category, Manufacturer name, country of origin, Intended Use, Composition, Mechanism of action, packaging, labeling and instructions for use The following procedure will be implemented: - Presentation to the pharmacology committee to evaluate whether or not the product has a pharmacological effect, in case the product has no pharmacological effect, it is presented to the specialized scientific committee to evaluate it Considering it is in a dosage form. And receiving the registration file of the device is permitted in case of the approval by the scientific committee approval and the notification of the specialized committee of medical devices registration In case the product has a pharmacological effect, it is presented to the specialized committee of medical devices registration
Hematology	
Transfusion Set	Standard filter mesh size ranges from 170-200µ and has to be mentioned on the package.
Apheresis Kit	Mention the following statement on the outer label (sales unit) in addition to the internal leaflet of all the Apheresis Kit regarding the period during which the kit will be used: «To be used within (…….) after opening the primary package»
Syringes	- Companies must describe the age stages on the outer package of syringes with their scientific name, where the word 'neonates', should be used instead of 'baby' for the age group 0-28 days, based on the World Health Organization's definition of age groups.
	- For the syringes going to be registered Samples should be brought from all different age groups (Pediatric, Adults, etc.).
Interventional & Diagnostic Radiation	
Core Biopsy Needles	To be presented to the Committee of Interventional and Diagnostic Radiology
Angiographic Catheter	It is necessary to specify whether it is compatible with lipiodol or not on the device package in the case of locally manufactured devices, or to mention that in the IFU or labels in the case of imported devices.
Urology	
Any product presented for Re- Registration	Safety reports shall be brought from the places which the device was supplied to in the last three years.
IIb, III & Implantable Medical Devices presented for New Registration	Any of the following shall be brought: Long-term Scientific Papers on Safety & Efficacy & Clinical Trials published in reputable journals. It is preferable to bring a summary of market history that the committee takes it into account (places where the device was previously used) in reference countries, although this record is not obligatory. Or the product is be produced by an international company with a good reputation in the international market.
Urine Collection Bags	It must be stated and clearly identified on the package whether it is sterile or not, and the two categories shall be differentiated by color

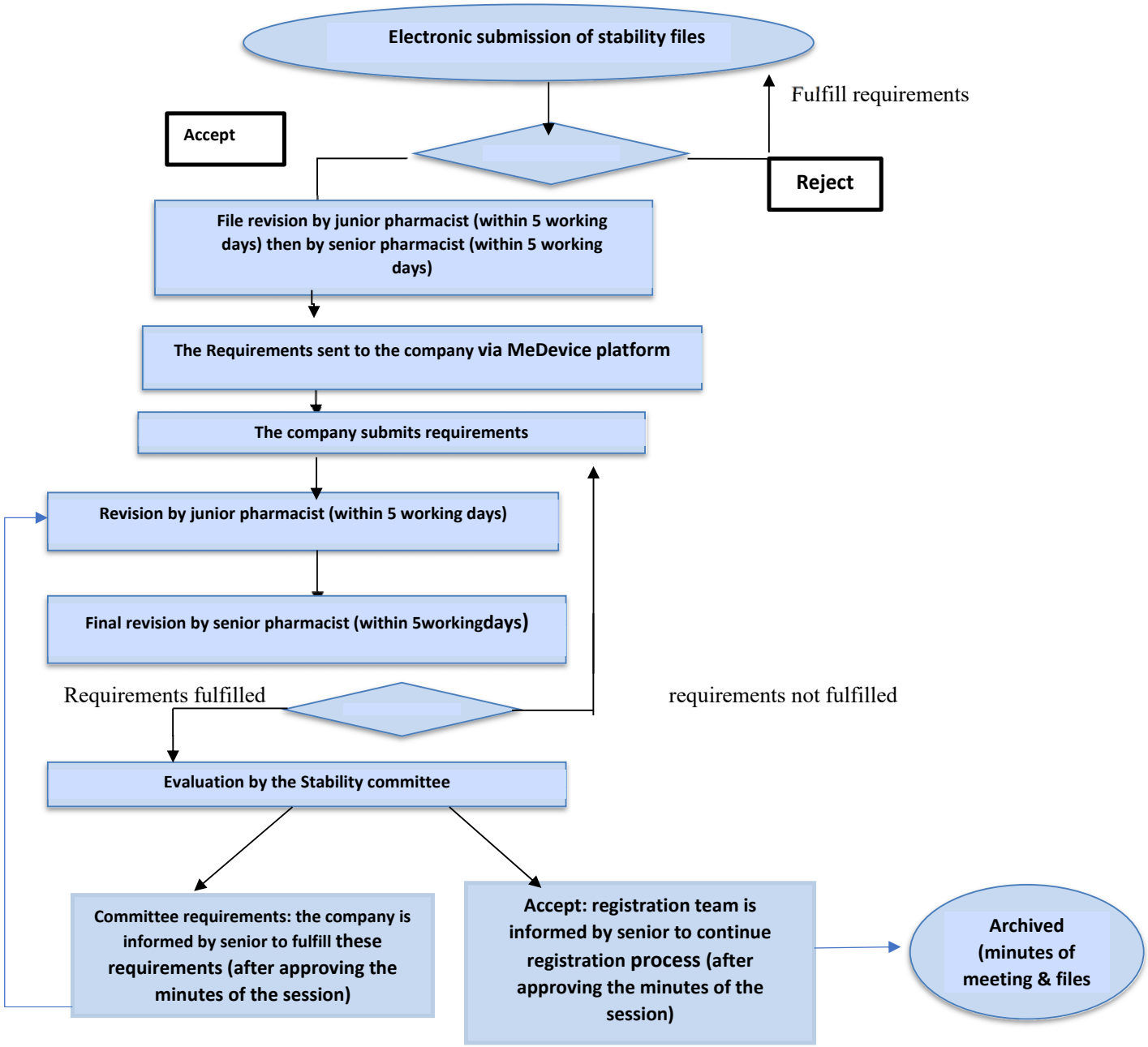
Surgery	
Surgical Sutures	Regarding **Surgical** sutures: - Those imported from non-reference countries: - A tensile strength test shall be done for one size of each surgical suture before and after registration (new registration / re-registration), and this test is required to be proven in the reports received from the Central Administration for Drug Control in addition to other tests carried out by the Central Administration for Drug Control, provided that the reports received during the course of registration procedures shall be presented to the specialized scientific committee of General and Plastic Surgery. - Those imported from reference countries - regarding the surgical sutures submitted for registration (new registration / re-registration), this test shall be done on them after registration for only one size of the type of the surgical suture subjected to registration and this test is required to be proven in the reports received from the Central Administration for Drug Control in addition to other tests carried out by the Central Administration for Drug Control.
Dermal Fillers	* The following warning shall be placed in a clear place on the outer package of all Dermal Fillers 1- It is forbidden to inject the device into blood vessels. 2- This device is used by licensed physicians only. * Recommendations issued by the specialized scientific committee of General and Plastic Surgery for Dermal Fillers shall be applied regarding the following: - The ID of the device shall be added inside the package, which determines the batch number so that the treating physician can track and identify the device used for the patient in case of any complications. Where the companies importing the dermal fillers are obligated to keep batches records that have been distributed to supplying places, this record should include all user's data in accordance with the tracking system (recall system) of each company, so that the Central Administration of Operations can follow them up. - In case it is mentioned that the Dermal filler has a corrective action in the internal leaflet, it is required to bring scientific studies published in reliable international scientific journals to prove and clarify the corrective action.
Sterile Dressings	The statement (All dressings shall be used under medical supervision) shall be added to the sales unit of the sterile dressings, provided that the implementation of this decision shall be monitored through the Central Administration of Operations.
Stainless steel Sutures	Stainless Steel Suture is used only in STERNUM. It is not permitted to mention the following use in the indications of use: Abdominal Wound Closure, Intestinal Anastomosis & Hernia Repair

2 Rows Staplers	New registration /re-registration files are received for Open surgery, Linear or Articulating 2 double staggered rows staplers + their reloading units. It is required to present them to the specialized scientific committee for general and plastic surgery, whether these devices are imported from reference or non-referential countries, so that the committee shall express a scientific opinion thereon, and in case the scientific committee approves them, the registration procedures shall be proceeded. - It is required to determine the situation of the reloading units specialized for the staplers before presenting them to the scientific committee. - It is required to determine whether the staplers are used in endoscopic surgeries or open surgeries before presenting them to the scientific committee. - It is required to determine whether the staplers are skin staplers or not by the company on the company's documents before presenting them to the scientific committee
Orthopedics	
Implantable Sterile Medical Products	1- The Free Sale, CE & ISO 13485 certificates shall be presented along with submitting summary of market history from a reference country, as well as submitting Long-Term Scientific Papers on Safety & Efficacy & Clinical Trials Published in Reputable Journals. 2- Tests done on the devices to be registered should be brought from one of the laboratories accredited by the International Laboratory Accreditation Cooperation (ILAC) - In addition, tests shall be done in any of the Faculties of Engineering and shall be evaluated by the scientific committee.
Implantable Non-Sterile Medical Products	- Tests (as per the manufacturing specifications) done on the devices to be registered should be brought from one of the laboratories accredited by the International Laboratory Accreditation Cooperation (ILAC) - In addition, tests shall be done in any of the Faculties of Engineering and shall be evaluated by the scientific committee. Medical devices that have a legal manufacturer in a reference country and an actual manufacturer in a non-reference country shall be exempted from submitting the following: - summary of Market history from a reference country along with submitting Long-Term Scientific Papers on Safety & Efficacy & Clinical Trials Published in Reputable Journals - Tests on the devices to be registered shall be done in one of the laboratories accredited by the International Laboratory Accreditation Cooperation (ILAC) and shall be evaluated by the scientific committee. - Tests of the Faculties of Engineering.

Ophthalmic Sutures from Non -Reference country	-A tensile strength test shall be done for all sizes of Ophthalmic Sutures before and after registration (new registration /re-registration), and this test is required to be proven in the reports received from the Central Administration for Drug Control in addition to other tests carried out by the Central Administration for Drug Control, provided that they shall be presented to the specialized scientific committee of ophthalmology and eye surgery.
Trypan blue	Registration files can be received for devices containing TRYPAN BLUE at a concentration not exceeding 0.06% and devices whose indications of use are for the surgeries of cataract and the anterior segment of the eye.
Ectoin	New registration /re-registration files containing Ectoin will not be received.
Cardiology	
Silk Suture without needles	Silk Suture without needles can be received since it is used by specialists in the field of cardiovascular surgery in many fields, including but not limited to, in ligation of tubes during surgical operations.
Other devices	
Oral dosage form class I non sterile	Inquiry requests shall be submitted by the importing companies, including the following: - Soft and hard copy of: Trade name, Class, Product category, Manufacturer name, country of origin, Intended Use, Composition, Mechanism of action, packaging, labeling and instructions for use The following procedure will be implemented: - Presentation to the pharmacology committee to evaluate whether or not the product has a pharmacological effect in case the product has no pharmacological effect, it is presented to the specialized scientific committee to evaluate it Considering it is in a dosage form And receiving the registration file of the device is permitted in case of the approval by the scientific committee approval and the notification of the specialized committee of medical devices registration In case the product has a pharmacological effect, it is presented to the specialized committee of medical devices registration
Obesity products	Inquiries requests shall be submitted by the companies' importing devices that are used to treat obesity and that are classified as a medical device in their country of origin, and they will be presented to the competent specialized committees before deciding. It's registration situation.

6. Procedures and rules regulating the specialized scientific committee for evaluating stability and biocompatibility studies.

Flow Chart (5) of Stability Committee for Medical Devices



presentation to the specialized scientific committee of evaluating stability and biocompatibility studies is required in the following cases:

1- Locally manufactured medical devices submitted for registration or re-registration that are not traded in one of the reference countries (i.e., do not have a free sale certificate from one of the reference countries or do not have a 510K (FDA Clearance) certificate).

2- Registered devices that are submitted to the Department of Variations for modification (i.e., changing or adding a package - changing or adding a sterilization method - changing storage conditions).

3- Shelf-life extension of a medical device (re-registration/variations).

4- Registered devices that are submitted to the Department of Variations for correcting the shelf-life period as a result of an error in the shelf-life certificate provided by the company.

Action Steps:

1- The file shall be submitted on the platform medevice.edaegypt.gov.eg in accordance with the check list (Appendix 5).

2- The stability file will be accepted if it fulfills all the items mentioned in the check list.

3- The stability file is evaluated within 10 working days.

- In case there are some missing requirements, they shall be fulfilled and submitted on the platform medevice.edaegypt.gov.eg, so they will be reviewed and the registration applicant shall receive a response within 5 working days from the date of submission.

4. After fulfilling all requirements, the file shall be presented to the specialized scientific committee of evaluating the stability and biocompatibility studies of the medical devices.

5. In case the committee approve the file, the registration procedures shall be completed, but if some documents are required to be provided, the company shall be notified.

- **General requirements regarding the specialized scientific committee of evaluating stability and biocompatibility studies:**

First: When the local factories present a stability study of any medical device to be evaluated by the specialized scientific committee of evaluating stability and biocompatibility studies of medical devices, they must submit the following:

- Stability studies of locally manufactured medical devices are required to be presented to the specialized scientific committee of evaluating stability and biocompatibility studies and they should be accompanied by samples sealed by the Central Administration of Operations, and stamped by the entity that conducted the study (the factory/a certified laboratory), provided that this sample shall be kept in the factory throughout the validity period of the registration license of the medical device, this procedure shall be followed up by the Central Administration of Operations, where the factory is obligated to submit this sample with a lot number identical to the number that was mentioned in the stability study submitted for presentation to the specialized scientific committee of evaluating the stability and biocompatibility studies of medical supplies.

This decision shall be applied to stability studies conducted after 2/1/2018

- The seizure record attached to the sample sealed by the Central Administration of Operations.
- The checklist template issued by the Central Administration of Operations, which was applied to the factory laboratory in which the stability study was conducted.

Second: A real time stability study must be submitted for the medical devices submitted for re-registration.

Third: Regarding the storage conditions mentioned on the outer package of locally manufactured medical devices:

i. Stability studies conducted at storage conditions of 30 C°±2, RH 65±5% must be submitted as the Arab Republic of Egypt falls within Zone Iva.

ii. Regarding the storage conditions mentioned on the internal labels of the medical devices, the manufacturer must place a guiding symbol on the label of the medical device stating that the maximum temperature for storing the medical device is 30˚  , or it shall clearly indicate the following statement on the label of the medical device (Upper limit of temperature = 30˚).

iii. In case the manufacturer desires to place a guiding symbol  stating the (upper and lower limits of temperature), the manufacturer must provide evidence of the stability of the medical device at the temperatures mentioned in the guiding symbol.

iv. The manufacturer must store the medical device under the storage conditions stated on the internal labels of the medical device and mentioned in the registration license, where the storage of the medical device under those condition will be followed up by the Central Administration of Operations

Fourth: In case the company cannot conduct the stability study or some of the tests, it may conduct the tests in an accredited entity that is approved for this purpose, provided that the company shall submit a qualification/accreditation certificate of the entity issuing the stability study in accordance with the international standard ISO-17025 issued by the accreditation body, along with providing the proof that the scope of accreditation of this entity includes its accreditation to conduct the tests provided. the results of these tests must be under the responsibility of the producing company. In this case the results of these tests can be included as part of the stability study of the product.

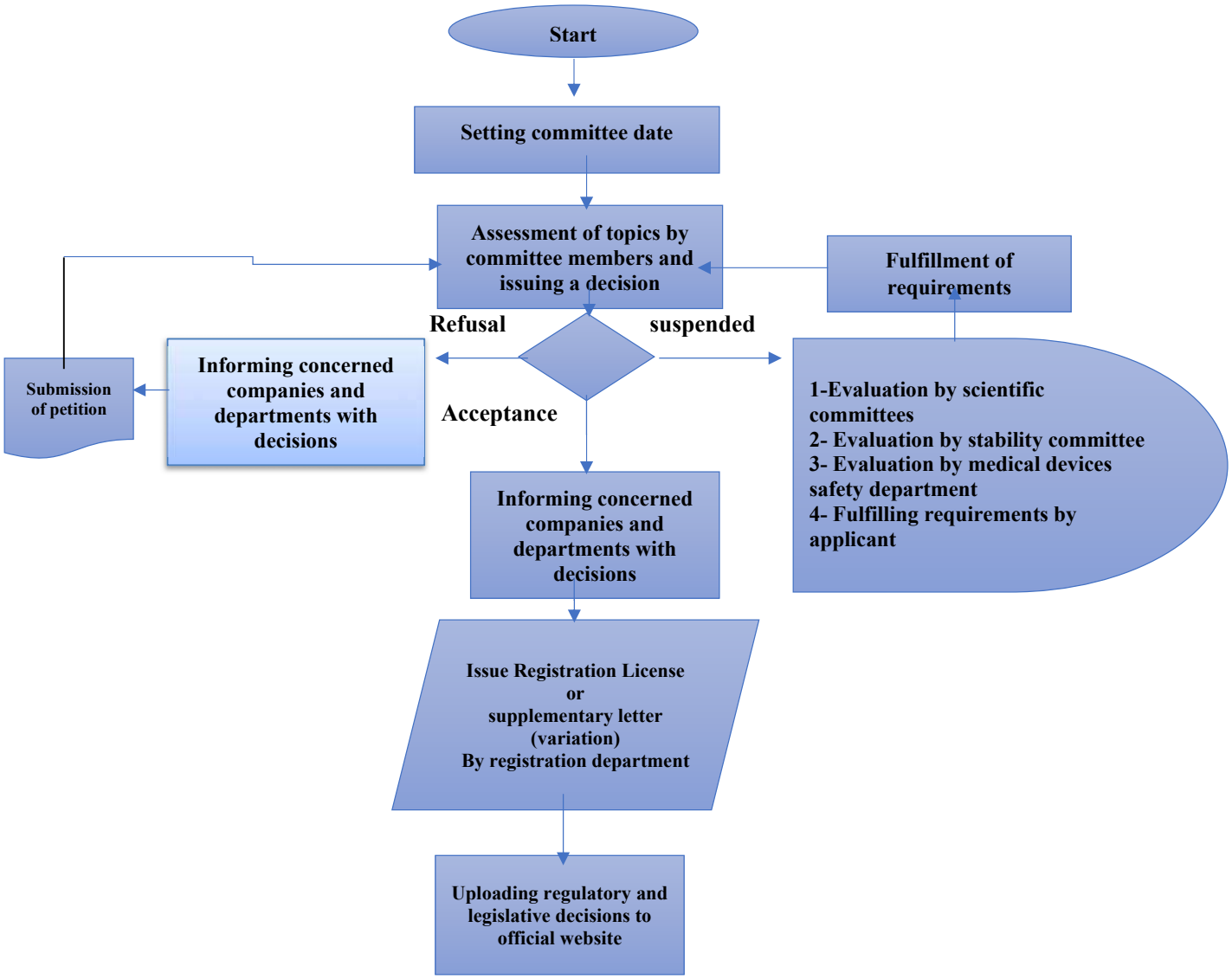
Fifth: The biocompatibility study must be conducted by an accredited entity that is approved for this purpose, provided that the company shall submit a qualification/accreditation certificate of the entity issuing the study in accordance with the international standard ISO-17025 issued by the accreditation body, along with providing the proof that the scope of accreditation of this entity includes its accreditation to conduct the tests provided. the results of these tests must be under the responsibility of the producing company.

Sixth: It is required to identify the sterilization method of the medical device that is being tested in all studies related to Sensitization & Irritation tests

Seventh: Medical devices imported from reference countries and submitted to the Department of Variations are exempted from submitting a biocompatibility study when presented to the specialized scientific committee of evaluating stability and biocompatibility studies of the medical devices.

7. Procedure of the specialized committee for registering the medical devices

Flow Chart (6) of specialized committee on registration of medical devices



8. Safety of medical devices:

A file shall be submitted to the Medical Devices Safety unit in the following cases only:

Medical devices classified as class IIb, or III and medical devices classified as class I, IIa with regulatory actions, this is for the following medical devices:

- Imported medical devices submitted for registration/re-registration.
- locally manufactured medical devices submitted for re-registration.

Also, safety declarations should be provided by the manufacturer in the following cases:

- Imported medical devices submitted for registration or re-registration and locally manufactured medical devices submitted for re-registration in all their classes.
  - In case of applying for registration/re-registration, the importing company is obligated to submit a commitment that it has a vigilance system in place for medical devices and that it follows up all its activities and requirements in accordance with the guidelines of the medical devices vigilance system with the Medical Devices Safety Unit- the Egyptian Pharmacovigilance Center.
  - The company must report any recall, FSN, or FSCA procedures that take place globally, or any incidents being monitored in the Arab Republic of Egypt to the Medical Devices Safety unit the Egyptian Pharmacovigilance Center, in accordance with the time periods specified in the guidelines for the Medical Devices Vigilance System.

Forms of Declarations of Safety (Appendix 6)

9. Issuance of registration license:

After completing the required documents of the registration file and paying the fees and service consideration, a registration report is issued for the medical device, valid for 10 years

10. Procedures of re-registration:

- Re-registration of medical devices shall be every 10 years based on a request submitted to the Central Administration for Medical Devices. Initial acceptance of the request is required to be within the first 3 months of the last year of the registration license validity.
- The applicant has to submit the re-registration file in accordance with the check list of the required documents.
- Service consideration shall be collected in accordance with the decree issued by the Chairman of the Egyptian Drug Authority in this regard.
- For the re-registration of locally manufactured medical devices and medical devices imported from non-reference countries, it is not required for them to be re-evaluated by the scientific committees in case of receiving reports from the Safety Department indicating that the documents have been accepted, and no regulatory actions have taken place for the device, along with the absence of any modification in the registered device in terms of composition - usage - design – classification.

- For locally manufactured medical devices that are subjected to presentation to the Scientific Committee of evaluating stability studies:

- These medical devices shall not be presented to the scientific committee of evaluating stability studies in case that no modification has occurred in the raw materials of the package and in case a real time stability study has been submitted during the registration for the first time or during the period of the registration license validity.
  - In case a real time stability study is not submitted during the registration for the first time or during the period of the registration license validity, it will be evaluated during re-registration.
- In case a change has occurred in the raw materials: the biocompatibility study shall be re-evaluated by the scientific committee of stability.
- In case of changing the sterilization method: the following shall be re-evaluated by the scientific committee of evaluating stability studies:

New stability study including sterilization validation only and re-revaluation of biological risk assessment.

- In case a change has occurred in packaging material or packaging dimension, the following shall be re-evaluated by the scientific committee of evaluating stability studies:

New stability study including packaging validation only and re-evaluation of biological risk assessment.

- In case of changing the shelf life and/or storage conditions: the following shall be evaluated by the scientific committee of evaluating stability studies:

New stability study and re-evaluation of biological risk assessment.

- The applicant has to complete the re-registration procedures within one year from the date of the expiry of the registration license period, and trading is permitted for him during this year. Upon the expiration of this period, if the requirements of the final file of re-registration are not fulfilled, the request will be considered as cancelled and the Central Administration of Operations will be notified. The request shall be renewed based on a formal request submitted by the company and repayment of the registration fees. The file shall be re-received and a one-year period will be granted to complete the re-registration requirements.

11. General requirements:

1. Medical devices must share the following criteria to be registered as a medical device with a single registration number:

Trade name, GMDN or UMDN Code, classification, intended use, manufacturer, Raw materials and age group (except for differences in sizes).

Sutures shall not be separated if their Raw materials are different and a single registration license will be granted.

• In case the medical devices differ in the abovementioned elements, they will be registered as separate medical devices and each medical device shall be given a separate registration license with a separate registration number.

2. In case the medical devices share the abovementioned elements but vary in any other difference, these devices shall be presented to the specialized scientific committee to study these differences and determine whether or not the differences are considered substantial, and then separating the devices and registering each device separately.

3. Requirements for registering orthopedic devices as a system:

- Applied to joints, screws and plates.
- The original catalog provided by the shall be attached to the registration file, in order to ensure that the parts intended to be registered as one system are identical with the catalogue, and the producing company shall provide a proof indicating that the parts intended to be registered are parts of one system, based on the decision of the Specialized Scientific Committee of Orthopedic Diseases and Surgery.
- Each device submitted for registration shall be presented separately to the Specialized Scientific Committee of Orthopedic Diseases and Surgery.
- The medical devices submitted for registration shall be considered as a system based on CE design examination certificate, or certificate of free sale, or the FDA certificate, provided that the parts of each system with their codes shall be clearly stated in certificate of free sale or the FDA certificate.

4. The original registration license belongs to its owner and any copy with another agent/distributor will not be taken into account.

5. It is not permissible to make any deletion or change in the data of the registration license, otherwise it shall be considered as invalid.

6. Medical devices taken through the oral/nasal/auricular route will be analyzed during their registration procedures.

7. The validity period of the registration license expires ten years from the date of registration, and the initial acceptance of the request is required to be within the first 3 months of the last year of the registration license validity.

8. It is not permitted to advertise medical devices in any media outlet except after obtaining a written approval from the competent administration of the Egyptian Drug Authority.

9. The registration license is issued in accordance with the quality certificate issued for the device. The foreign manufacturer and the importer are fully responsible for the validity and technical safety of the device and any defects or dangers resulting from its use falls under their own responsibility.
10. Registration department shall be dealt with by an official delegation issued for the company's representative with a bank authentication (valid signature).
11. It is not permissible to make any change in the medical device except after obtaining the approval of the Central Administration for Medical Devices in accordance with the applicable procedures as per the type of change, otherwise the registration license shall be cancelled.
12. Recall system shall be applied.
13. The company must implement safety requirements.

14. Special requirements for some medical devices

Textured Breast Implant	The registration of any Textured Breast Implant, whether imported from reference or non-reference countries, is not accepted, because it has been proven to be dangerous globally and it causes large cell lymphoma.
` Textured Tissue Expanders	Files of registration/proceeding with registration procedures/importation of these devices is not accepted.
Injectable Permanent Soft Tissue Dermal filler	Any "Injectable Permanent Soft Tissue Dermal filler" shall not be received, as the incidence of serious complications resulting from its injection is very high, which has led to a consensus by many international scientific studies that it shall not be used due to its danger.
Laparoscopic 2 rows stapler	Files of new registration/re-registration of any Laparoscopic 2 rows stapler that is used in the digestive system shall not be received.
Surgical Powdered Latex Gloves	Files of new registration of Surgical Powdered Latex Gloves shall not be received.
Steel Lancet	Files of new registration of any Steel Lancet device shall not be received, because there are more convenient alternatives, less painful, and less susceptible to contamination, and because this steel lancet devise causes a wound that is more serious than that caused by other types, and diabetic patients' wounds do not heal easily.
Surgical needle (A needle without suture)	This device has no use in modern medicine, and when connected with suture, it requires making a knot, which causes tissue rupture.
Syringes without needle	- Files for new registration/re-registration of syringes without needles for intravenous, intramuscular or subcutaneous injection shall not be received.
Insulin syringes (Grade 40 or double grade)	- No appointments will be given or files receiving No proceeding with registration procedures shall occur for double-graded syringes. - Insulin syringes other than those with 100-unit size Is not permitted.

12. A List of documents required to register medical devices and appendices of requirements

Appendix (1): List of documents required to register/re-register **sterile or non-sterile imported medical devices**

1- payment receipt of registration/re-registration fees.

2- The original delegation letter approved by the Chairman of the Board of Directors, with bank authentication of the signature of the person responsible for dealing with the Medical Devices Registration Department and receiving registration license.

3- A declaration to adhere to safety procedures in accordance with the announcement issued by the General manager of the Egyptian Pharmacovigilance Center and approved by the head of the Administration on 04/24/2018 and 08/08/2019.

4- For companies, the following are required:

-a legalized letter delegating the importing company to register in which the name of the device is mentioned, including the trade name of the device, issued by: the legal manufacturer or whomever delegated by the legal manufacturer under a legalized relationship

or by the parent company or whomever it delegates under a legalized relationship (the relationship letter should mention the parent company, the legal manufacturer, and the entity responsible for issuing the registration delegation, clarifying the name and address of each one of them).

- The renewed commercial record of the importing company and the importer license of the registration applicant.

or

The importer license with the name of the manufacturer or the name of the distributing company based on the relationship letter between the manufacturer and the supplier.

- A legalized distribution or agency contract with the foreign supplier directly that is valid and has a specified time period.

- The relationship between the foreign manufacturer and the foreign distributor or supplier, if any, that explicitly stipulates the right of the foreign distributing or supplying company to conclude contracts and external agencies on behalf of the manufacturer, this relationship must be legalized.

For scientific offices, the following are required:

- A scientific office license.

- A relationship, if any.

Scientific offices registering medical devices produced by companies that are not a branch of the parent company of the scientific office shall submit the following:

- A legalized letter from the legal manufacturer of the medical devices delegating the scientific office to register for it in Egypt.
- A legalized letter issued by the parent company for the scientific office stating that it has no objection that the company owning the medical devices will delegate the scientific office to register its devices in Egypt.
- The original delegation letter approved by the Chairman of the Board of Directors, with bank authentication of the signature of the person responsible for dealing with the Medical Devices Registration Department and receiving registration reports.

- A declaration to adhere to safety procedures in accordance with the applicable procedures followed by the Egyptian Pharmacovigilance Center.

2- The required certificates shall be valid for a period of not less than 3 months from the date of submitting the file:

* It is not required to legalize medical devices' quality certificates (CFG from FDA, CE, ISO 13485:2016 certificate or EN ISO 13485:2016 FRRESALE certificate) from (the Chamber of Commerce and the Egyptian Embassy in the country of origin) which are issued by the reference countries and which the administration has verified their authenticity from bodies that issue these certificates. In case that the issuance validity of these certificates is not confirmed by these bodies, these certificates shall be submitted with the legalization of the Chamber of Commerce and the Egyptian Embassy. case that the body does not respond within 3 months from the date of receiving the file, the file shall be saved and it shall be resubmitted again after the legalization in accordance with the checklist of documents announced at the time of resubmission.

• **Note**: CFG certificates from USFDA are not required to be legalized by the Chamber of Commerce and the Egyptian Embassy in case that the device data mentioned therein is verified through the website of both the FDA CDRH Export certificate validation and the Premarket Notification (510k) for medical devices classified as Class II and through FDA CDRH Export certificate validation and the Premarket Approval (PMA) for medical devices classified as Class III.

1) **The free sale certificate** that is issued by the Ministry of Health of the country of origin if it is a reference country (or a free sale certificate from one of the reference countries if the country of origin is a non-reference country) and that includes the trade name, codes or sizes of the device and contains the legal manufacturer and the actual factory manufacturer (if any).
OR
2) **The CFG certificate that is issued by the USFDA** for the device and that includes the trade name and the codes of the devices and contains the legal manufacturer and actual manufacturer (if any).

(In case that this certificate is obtained, the CE certificate is not required, .and also the ISO 13485 certificate is not required in case the FDA certificate mentions that the plant at that time appeared to be in compliance with current good manufacturing practice requirements.

2) **The CE certificate**: of the finished product, with all its components, accessories, and models, that is issued by (a notified body), taking into account the Annex of the specification (Annex) as per the product classification.
If the device contains a material of bovine animal origin, the CE certificate must contain: EU722/2012 (The Regulation replaces the Commission Regulation existing requirements contained in Directive 2003/32/EC concerning medical devices manufactured utilizing tissues of animal origin) TSE-susceptible animals in medical devices.
** It is not required to submit a CE certificate for Class I - Non-Sterile medical devices.
4) **The ISO 13485: 2016 certificate** or the EN ISO 13485: 2016 certificate issued by an internationally accredited certification body, provided that it covers the product category.
5) **The Declaration of Conformity Certificate**, stamped and signed by the legal manufacturer, which includes the trade name, codes, or sizes of the device, and includes kit/set contents in the case of kit/set, provided that the following is mentioned:
The Quality is under the responsibility of the foreign manufacturer, the notified body, the CE certificate number of the device, the indication of use, classification, and it should contain the actual manufacturer, if any or to be mentioned in an attachment for declaration

According to Canadian regulations

1- Declaration of conformity according to Canadian regulation

Acc. to the form https://www.canada.ca/en/health-canada/services/drugs-healthproducts/medical-devices/application-information/forms/declaration-conformity-forms-medicaldevices.html

2- Manufacturer certificate to cover export of medical devices issued from: The Health Products and Food Branch Inspectorate (HPFBI), Health Canada.

3-Medical device active license for medical devices class II, III, and IV.

4-Medical device establishment license for medical device class I.

5-ISO 13485:2016 certificate.

6- Declaration letter mentions full medical device list submitted to the Egyptian drug authority in case medical device active license is issued for medical device family, medical device group, or medical device group family, this declaration letter will be sent to the health Canada to confirm that the license covers the entire medical device list

contents of the technical file on the legal manufacturer's letterhead, stamped and signed by the legal manufacturer and containing the trade name of the device:

1) (R.M composition) certificate.

2) Analysis certificate of the device: physical-chemical-biological

• Covering letter for the analysis confirming that applied method is according to manufacturing standard and under the manufacturer's responsibility (mentioning all the manufacturing standards)

• The analysis certificate included in the file shall be sufficient, based on a letter from the manufacturing company stating that the method used is in accordance with manufacturing standards and under the manufacturer's responsibility.

3) Sterilization certificate of the device.

It is not required in the case of non-sterile medical devices.

4) A certificate of Packaging material & Number of units per pack

5) A description of the data on the inner and outer label of the package (Outer &Inner Label), a sample of the (Master Label), the inner leaflet stamped and signed by the manufacturing company, and 2 copies of the original art work of the inner and outer package stamped and signed by the manufacturing company.

6) A catalog to describe the device, clarify its parts, and be used in case a clarification is required.

7) The original IFU of the device that is approved, signed and stamped by the manufacturing company.

- In the case of electronic labeling, the IFU from the foreign manufacturer shall be submitted in the medical device registration file and will be attached to the registration license after its issuance, along with the artwork that is approved by the legal manufacturer and that includes the following statement:

(Instruction for use in printed paper form can be provided at the latest within 7 calendar days of receiving a request from the user).

8) The shelf-life certificate of the product stating the product's trade name and storage conditions.

9) the original license of previous registration in the case of re-registration.

10) A sample of the device intended to be registered.

11) In case of the devices classified as Class I Non-Sterile, it is required to bring: Compliance with essential requirement and harmonized standards check list.

Appendix (2): List of documents required to register/re-register sterile or non-sterile locally manufactured medical devices

1- payment receipt of registration/re-registration fees.

2- The original delegation letter approved by the Chairman of the Board of Directors, with bank authentication of the signature of the person responsible for dealing with the Medical Devices Registration Department and receiving registration licenses.

3- A declaration to adhere to safety procedures in accordance with the announcement issued by the General manager of the Egyptian Pharmacovigilance Center and approved by the Head of the Administration on 04/24/2018 and 08/08/2019.

4- **The applicant**:

A- A local factory.

B- A free zone factory.

For local factories, the following are required:

The previous licensing system:

• The commercial record.

• The industrial facility license.

• The tax identification card.

• The factory license issued by the Egyptian Drug Authority.

In case of the free zone factories, the industrial facility license is not required. The license issued by the General Authority of Investment and Free Zones to practice the activity under the free zone system is required.

The current licensing system:

• Operating license from the Industrial Development Authority.

• The commercial record.

• The tax identification card.

• The factory data certificate issued by the Central Administration of Operations at the Egyptian Drug Authority.

5- A letter issued by the factory, signed and sealed, clarifying the steps the factory takes in manufacturing the devices submitted for registration.

6- The required certificates shall be valid for a period of not less than 3 months from the date of submitting the file:

i. The certificate of CE (Acc.to 93/42/EC): of the finished product, with all its components, accessories, and models, that is issued by (a notified body), taking into account the Annex of the specification (Annex) as per the product classification.

• If the product contains a material of animal origin, the CE certificate 722/2012 must contain:

Concerning active implantable medical devices and medical devices manufactured utilizing tissues of animal origin has been published in the Official Journal of the European Union, The Regulation replaces the existing requirements contained in Directive 2003/32/EC tissues from TSE-susceptible animals in medical devices.

** It is not required to submit the CE certificate for medical devices classified as Class I - Non-Sterile.

ii. ISO 13485: 2016 certificate delete issued by an internationally accredited certification body, provided that it covers the product category.

Or The following shall be provided:

510K (FDA Clearance) certificate issued by the US FDA, in addition to the EN ISO 13485: 2016 certificate issued by an internationally accredited certification body, provided that it covers the product category.

iii. The Declaration of Conformity Certificate, stamped and signed by the legal manufacturer, which includes the trade name, codes, or sizes of the device, and includes kit/set contents in the case of kit/set, and the following should be mentioned:

• The Quality is under the responsibility of the manufacturer.

• The notified body.

• The CE certificate number of the device.

• Classification & Indication of use and it should contain the actual manufacturer, if any, or to be mentioned in an attachment for declaration

7- contents of the technical file on the legal manufacturer's letterhead, stamped and signed by the legal manufacturer and containing the trade name of the device:

A- (R.M composition) certificate.

• Approved Supplier List.

• List of PVC codes& grade.

B- Sketch Diagram.

C- Analysis certificate of the product: physical – chemical biological:

**Covering letter for the analysis confirming that applied method is acc. to manufacturing standard and under the manufacturer responsibility (mentioning all the manufacturing standards)

The analysis certificate included in the file shall be sufficient, based on a letter from the manufacturing company stating that the method used is in accordance with manufacturing standards and under the manufacturer's responsibility according to announcement number 12 or the year 2012.

D- A copy of the stability study that shall be presented to the Committee of Stability Study in accordance with the guidelines regulating the work of the specialized scientific committee of evaluating biocompatibility studies of medical devices.

• It is not required to submit a Biocompatibility Test Report and stability study for medical devices submitted for registration or re-registration that are locally manufactured and traded in the reference countries.

• The manufacturer must prove the storage conditions mentioned in the stability study in the labeling of the medical device, and its compliance with the storage conditions will be followed up by the Central Administration of Operations.

E- A Sterilization certificate for the product.

F- A Certificate Packaging material & number of units per pack.

G- A description of the package's inner and outer label data (Inner & Outer labels)

H- A sample of the reference label (Master Label), the inner leaflet stamped by the manufacturer, and the original art work of the inner and outer package sealed stamped and signed by the manufacturer.

I- A catalog to describe the device, clarify its parts, and be used in case a clarification is needed.

J- The shelf-life certificate of the product stating the product's trade name and storage conditions.

K- The original expired registration license in case of re-registration.

L- A sample of the product intended to be registered.

** In case of the devices classified as Class I Non-Sterile, it is required to bring: Compliance with essential requirement and harmonized standards check list.

Appendix (3): List of documents required to register the medical devices using the F-Toll system (sterile and non-sterile)

1- payment receipt of registration/re-registration fees.

3- Adherence to safety procedures in accordance with the announcement issued by the General manager of the Egyptian Pharmacovigilance Center and approved by the Head of the Administration on 04/24/2018 and 08/08/2019.

3- The original delegation issued by the « registration license holder», approved by the Chairman of the Board of Directors and legalized by the notarization office of the Real Estate registration authority, with regard to the signature of the person responsible for dealing with the Medical Devices Registration Department and receiving registration license.

4- A Valid F-toll manufacturing contract between the «registration license holder» and the manufacturer", indicating the responsibility of both parties in terms of legality & technicality, signed and stamped by both parties, and legalized by the notarization office of the Real Estate registration authority, provided that the contract will be reviewed and approved through the Legal Affairs Department of the Egyptian Drug Authority, and that the contract shall include the following:

The «license holder» is fully responsible for the following:

• The product quality, sterility and all manufacturing steps, provided that the actual manufacturer shares the technical responsibility for quality.

• Registering the devices in the Egyptian Drug Authority and informing the Authority of any changes related to the devices.

• Issuance of the importing approval for production materials in the name of the actual manufacturer for the benefit of the «registration license holder» , provided that the incoming invoice shall contain the batch number of the raw materials.

• Distribution of the medical device, taking into account that the storage starting from the imported raw materials until the finished product is released should be in a licensed warehouse in accordance with the contract concluded between the two parties.

• Maintaining an original permanent record that includes the medical devices in which it deals with, the numbers and size of the batches, their manufacturing place, and the locations of their distribution throughout the registration period of these devices. These records will be periodically inspected at the headquarters of the «actual manufacturer » by the Central Administration of Operations in accordance with the rules, provided that a copy of the records should be available at the headquarters of the « license holder» .

• Implementing the quality system at the actual manufacturer. The Central Administration of Medical Operations has the right to verify the application of quality standards and procedures at the actual manufacturer, and the »registration license holder» shall take all the measures to facilitate the task of the Central Administration of Operations.

• Existence of a medical devices vigilance system, and the follow-up of all its activities and requirements in accordance with the guidelines of the medical devices vigilance system with the Medical Devices Safety Department.

• Reporting any recall, FSN, or FSCA procedures that take place globally, or any incidents being monitored in the Arab Republic of Egypt to the Medical Devices Safety unit in accordance with the time periods specified in the guidelines for the medical devices vigilance system.

• Providing the necessary assistance to representatives of the Central Administration of Operations when they pay a visit to inspect the production line by identifying a person who will carry out these tasks and be responsible for approving the technical file of the device.

In case of changing the person responsible for the production line, the Central Administration of Operations shall be notified.

• The registration license holder does not have the right to produce the same medical device using f-toll manufacturing system (as an actual manufacturer) for the benefit of another registration license holder.

• The actual factory where the manufacturing process take place has the right to produce only after the issuing of the registration license, provided that the actual should keep in its records the registration report.

• The party responsible for supplying the raw materials to the « factory» .

5- Regarding the «registration license holder »:

• The commercial record and the tax identification card, provided that they should include the activity of manufacturing medical devices using the F-toll-manufacturing system and trading.

• A medical devices/pharmaceuticals factory license in accordance with followed rules and it is not required to include the production line of the device intended to be registered.

6- Regarding the «factory»:

• A medical devices factory license in accordance with followed rules, provided that it must include the production line of the device intended to be registered.

• The commercial record and the tax identification card, provided that they should include the activity of manufacturing medical devices.

7- The required certificates shall be valid for a period of not less than 3 months from the date of submitting the file:

i. The certificate of CE (Acc.to 93/42/EC): of the finished product, with all its components, accessories, and models, that is issued by (a notified body), taking into account the Annex of the specification (Annex) as per the product classification.

* If the product contains a material of animal origin, the CE certificate 722/2012 must contain:

Concerning active implantable medical devices and medical devices manufactured utilizing tissues of animal origin has been published in the Official Journal of the European Union. The Regulation replaces the existing requirements contained in Directive 2003/32/EC tissues from TSE-susceptible animals in medical devices.

** It is not required to submit the CE certificate for the medical devices classified as Class I - Non-Sterile.

ii. The ISO 13485: 2016 certificate issued by an internationally accredited certification body, provided that it covers the product category.

or the following shall be provided:

A 510K (FDA Clearance) certificate issued by the US FDA, in addition to an EN ISO 13485: 2016 certificate issued by an internationally accredited certification body, covering the Product category.

iii. The Declaration of Conformity Certificate, issued, signed, and stamped by the «registration license holder », that states:

• Factory's/ name and address

• The detailed name of the medical device (the trade name, models, codes, or sizes of the device, and includes kit/set contents in the case of kit/set.

• Manufacturing standard.

• The Quality is under the responsibility of the «registration license holder » along with his commitment to the responsibilities specified in the contract.

• The name and address of registration license holder.

• The notified body.

• The CE certificate number of the device.

Indication of use & * Classification

8- An Approved Supplier List issued by the party responsible for supplying the raw materials, signed and stamped, and this party is the one responsible for the Supplier Qualification.

9- A delegation issued by the «_registration license holder », approved by the Chairman of the Board of Directors and authenticated by the notarization office of the Real Estate registration authority, with regard to the signature of the person responsible for approving the data of the technical file approved in the Registry of F- toll manufacturing, provided that he agrees to do so, along with mentioning his position in the factory, which qualifies him to approve this technical file.

10- The medical device technical file issued by the manufacturer, signed and stamped, provided that it should be accompanied by a certified letter from the «license holder/» , in which he undertakes his full responsibility for all the data contained in the attached technical file and mentions in all his documents the name of the medical device, including the following:

A- (R.M composition) certificate.

*List of PVC codes & grade

B- Sketch Diagram.

C- Analysis certificate of the product: physical – chemical biological:

*Covering letter for the analysis confirming that applied method is acc. to manufacturing standard and under the manufacturer responsibility (mentioning all the manufacturing standards)

The analysis certificate included in the file shall be sufficient, based on a letter from the manufacturing company stating that the method used is in accordance with manufacturing standards and under the manufacturer's responsibility according to announcement 12 for the year 2012.

D- A copy of the stability study that shall be presented to the Committee of Stability Study in accordance with the guidelines regulating the work of the specialized scientific committee of evaluating biocompatibility studies of medical devices.

• It is not required to submit a Biocompatibility Test Report and stability study for medical devices submitted for registration or re-registration that are locally manufactured and traded in the reference countries.

• The manufacturer must prove the storage conditions mentioned in the stability study in the labeling of the medical devices, and its compliance with the storage conditions will be followed up by the Central Administration of Operations.

E- A Sterilization certificate for the product.

F- A certificate of packaging material and number of units per pack.

G- A description of the package's inner and outer labels data. **(Inner &Outer Labels)**

A sample of the reference label (Master Label), and the inner leaflet stamped by the manufacturer, provided that both labels should mention the following phrase:

- Produced by (name of the "manufacturer") for the benefit of (name of "registration license holder").

- They should also mention the address of both the "manufacturer", and the "registration license holder" and the country of origin.

- A catalog to describe the device, clarify its parts, and be used in case a clarification is needed.

H- The shelf-life certificate of the product stating the product's trade name and storage conditions.

The original expired registration license in case of re-registration.

I- A sample of the product intended to be registered.

J- A letter issued by the manufacturer, signed and stamped, explaining the steps the manufacturer takes in manufacturing the devices submitted for registration.

K- A report from the Central Administration of Operations that clarifies the availability of the production line that does not have any violations that contradict with good manufacturing requirements (this shall be done by correspondence with the Central Administration of Operations).

In case of the devices classified as Class I Non-Sterile, it is required to bring: Compliance with essential requirement and harmonized standards check list.

Appendix (4) Documents required for presentation to specialized scientific committees

❖ **Firstly: Regarding the medical devices submitted for registration/re-registration**

One copy of each of the following documents should be submitted:

- Material composition certificate.

- Catalog & insert leaflet containing the intended use.

- Quality certificates, which include the following:

o Declaration of conformity.

o Free sale (from a reference country) + CE Certificate + ISO 13485.

o Certificate for foreign government from (US FDA) + ISO 13485 (If no GMP statement in FDA).

o A summary of market history may be required to be submitted and it should be stamped and approved by the places where the device has previously been used in a reference country, in addition to submitting clinical trials for the product published in reputable scientific journals on safety & efficacy in case the members of the scientific committee demand.

❖ **Secondly: Additional documents submitted as per the committee's specialization or the type of medical device:**

Surgical sutures **Specialized Scientific Committee of General and Plastic Surgery**	- A conformity issued by the Central Administration for Drug Control for only one size of each type of surgical sutures submitted for new registration/re-registration and imported from non-reference countries, including the tensile strength test in addition to other tests conducted by the Central Administration for Drug Control.
Specialized Scientific Committee of Nephrology Diseases and Surgery:	For medical devices submitted for re-registration, the following shall be provided: - A statement of supply orders during the past three years for any device submitted for re-registration, in addition to submitting a survey about the circulation volume, the device efficiency, and the side effects observed from the places that use the device and that are mentioned in the statement. Regarding devices submitted for new registration classified as Class IIb, III & Implantable, one of the following should be provided: - Long-term Scientific Papers on Safety & Efficacy & Clinical Trials published in reputable journals - It is preferable to bring a summary of market history that the committee takes into account (places where the device was previously used) in reference countries, although this document is not obligatory. - Or the product must be produced by an international company with a good reputation in the international market

I.V. Cannula **Specialized Scientific Committee of Anesthesia**	- Samples of all sizes must be provided.
Syringes **Scientific Committee of Hematology diseases**	- A sample from each age group must be provided.
Specialized Scientific Committee for Diseases and Surgery of the Digestive System and Liver	For medical devices imported from non-reference countries in all classifications (I, IIa, IIb & III), the following shall be provided: - **clinical trials published in reputable scientific journals.** - **An approved and stamped Summary of market history from centers and hospitals where the device has been used in the reference countries.**
Medical devices that are in a Dosage Form	- Material composition certificate. - Catalog & insert leaflet containing intended use. - Inner & outer labels
Pen Needles **Specialized Scientific Committee of Endocrine glands and Diabetes**	- The outer label of the pen needles, which mentions all the compatible types of pens that are used with them. It is not required to submit a sample of each type of pen mentioned on the outer label of the device. It is sufficient to submit random samples to be evaluated by the Scientific Committee.
Specialized Scientific Committee of Neurological Diseases	- For medical devices imported from non-reference countries that are implantable inside the body, the following shall be provided: A summary of market history (places where the device has been used) in European Union countries. Long-term Scientific Papers on Safety & Efficacy & Clinical Trials published in reputable journals
Staplers **Specialized Scientific Committee of General and Plastic Surgery**	A letter stating the following: - Identifying the type of staplers, whether they are 2 or 3 rows. - Identifying the type of staplers, whether they are laparoscopic or open surgery. - Determining the registration situation of the reloading units specialized for the stapler submitted for presentation.

❖ **Thirdly: Regarding orthopedic devices that are implanted inside the body:**

A- Regarding locally manufactured orthopedic devices:

Medical Device Type	Sterile Medical Devices	Non-Sterile Medical Devices
procedures		After the company obtains an appointment to submit the registration file: Applicable procedures for obtaining importing approval shall be followed until the license, is issued.
During registration	1- Approval of the approved raw material supplier list by the Scientific Committee of Orthopedic Diseases and Surgery, provided that the relevant central administrations shall be notified. 2- Implementing the decision of the specialized committee of medical devices registration on 03/15/2018 as follows: A. The Central Administration of Operations shall draw the necessary samples to conduct tests on them in one of the laboratories accredited by: International Laboratory Accreditation Cooperation (ILAC) In addition to, conducting analysis in any of the Faculties of Engineering. B. In case that there are no accredited laboratories in the Arab Republic of Egypt: Samples shall be exported abroad after the company obtains the approval of the Export Administration to conduct the tests on them, under the manufacturer' responsibility. C. The accredited laboratory shall send the tests' results to the Medical Devices Registration Department to be presented to the Orthopedic Scientific Committee for evaluation. D. Making sure that that all procedures, documents and tests include the same batch numbers that were drawn. And If it is proven that there has been tampering with the samples or tests results, the appropriate legal measures shall be taken in this regard. 3- Implementing safety procedures during the registration in accordance with the measures followed in this regard.	
After obtaining the registration Report	The applicable rules shall be applied, where the Central Administration of Operations draws random samples to conduct all the chemical, physical, and engineering tests (as per manufacturing standard) in any of the Faculties of Engineering, in exchange with the Central Metallurgical Research Institute (in case it is approved to conduct tests on the finished product and not on raw materials) and in exchange with the Central Administration of Drug Control. Note: The company is not obligated to analyze performance and physical tests in an accredited laboratory again except if it adds a new supplier different from the one approved by the Scientific Committee	

B- Regarding orthopedic devices imported from non-reference countries:

Medical Device Type	Sterile medical devices	non-sterile medical devices
Procedures		**<u>After the company obtains an appointment to submit the registration file:</u>** Applicable procedures for obtaining importing approval shall be followed until the registration license, is issued <u>Note:</u> **The safety and efficacy of the devices will be surveyed in the hospitals which they are supplied to through the Safety Department one year after the approval by the Scientific Committee to obtain importing approval. the safety reports will be evaluated by the Scientific Committee.**
During registration	**1- The applicable procedures for obtaining registration license shall be followed, along with submitting the Free Sale, CE & ISO 13485 certificates in addition to submitting a summary of market history of the device from a reference country, as well as submitting** **Long-Term Scientific Papers on Safety & Efficacy & Clinical Trials Published in Reputable Journals** **2- Providing tests for the devices intended to be registered from one of the laboratories accredited by the International Laboratory Accreditation Cooperation (ILAC).** **In addition to, conducting tests in any of the Faculties of Engineering so they will be evaluated by the scientific committee.**	**Providing tests (as per the manufacturing standard) for the devices intended to be registered from one of the laboratories accredited by the International Laboratory Accreditation Cooperation (ILAC). In addition to, conducting tests in any of the Faculties of Engineering so they will be evaluated by the scientific committee.**
	<u>Medical devices that have a legal manufacturer in a reference country and an actual manufacturer in a non-reference country shall be exempted from submitting the following:</u>	

	- A summary of market history for the device from a reference country as well as submitting **Long-Term Scientific Papers on Safety & Efficacy & Clinical Trials Published in Reputable Journals** **- Tests on the devices intended to be registered by one of the laboratories accredited by the International Laboratory Accreditation Cooperation (ILAC) and evaluating them by the scientific committee.** **- Tests conducted in the Faculty of Engineering.**
After obtaining the registration license	The applicable rules shall be applied, where the Central Administration of Operations draws random samples to conduct all the chemical, physical, and engineering tests (as per manufacturing standards) in any of the Faculties of Engineering, in exchange with the Metallurgical Research Institute (in case it is approved to conduct tests on the finished product and not on raw materials) and in exchange with the Central Administration of Drug Control.

*** Appendix (5): List of documents required for presentation to the specialized scientific committee of evaluating stability and biocompatibility studies for locally manufactured medical devices.**

1- Stability study.

2- Biocompatibility Study.

*** NB:**

The sterilization method of the medical device being tested is determined in all studies of Sensitization & Irritation tests in accordance with the international standard (Page 28 /A.5) ISO 10993-10: 2010.

3- The raw material composition certificate of the medical device.

4- Analysis certificate of the medical devices.

5- A certificate of Packaging materials & number of units per pack.

6- Sterilization certificate of the medical device.

7- The shelf-life certificate of the medical device.

8- Quality certificates of the medical device (Declaration of Conformity, CE, ISO-13485:2016, Free sale or FDA).

9- In case of re-registration, a copy of the previous registration license is required.

10- Stability studies of locally manufactured medical devices are required to be presented to the specialized scientific committee of evaluating stability and biocompatibility studies and they should be accompanied by samples sealed by the Central Administration of Operations, and stamped by the entity that conducted the study (the factory/a certified laboratory), provided that this sample shall be kept in the factory throughout the validity period of the registration license of the medical device, this procedure shall be followed up by the Central Administration of Operations, where the factory is obligated to submit this sample with a lot number identical to the number that was mentioned in the stability study submitted for presentation to the specialized scientific committee of evaluating the stability and biocompatibility studies of medical supplies.

• Regarding submitting that sample with a lot number identical to the one mentioned in the stability study submitted for presentation to the specialized scientific committee of evaluating the stability and biocompatibility studies of medical devices, that decision shall be applied to the stability studies that will be conducted after the decision is published on the electronic website of the Central Administration of Medical Devices (02/01/2018).

11- The seizure record attached to the sample sealed by the Central Administration of Operations and the checklist template issued by the Central Administration of Operations, which was applied to the factory laboratory in which the stability study was conducted.

12- In case the company cannot conduct the stability study or some of the tests it may conduct the tests in an accredited entity that is approved for this purpose, provided that the company shall submit a qualification/accreditation certificate of the entity issuing the stability study in accordance with the international standard ISO-17025 issued by the accreditation body, along with providing the proof that the scope of accreditation of this entity includes its accreditation to conduct the tests provided. the results of these tests must be under the responsibility of the producing company. in this case the results of those tests can be included as part of the stability study of the product.

Appendix (6): Declarations of the safety of medical devices

(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)

(Date)

In case of there is a legal representative of the legal factory, the following declaration shall be submitted:

(COMPANY NAME)

(Date)

Manufacturer's Commitment About Safety Of Medical Devices

For MDs Class I and IIa

Declaration (1)

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) is responsible that there is a vigilance system in place, and for the oversights of 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

In case of there is a legal representative of the legal factory, the following pledge shall be submitted:

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,

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 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) is responsible that there is a vigilance system in place, and for the oversights of 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 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,

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 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)

[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)

11. A list of abbreviations

Acronym	Definition
510 K	Premarket Notification
Accessory	An extra equipment piece specifically manufactured to be used with a medical device
AIMD	Active implantable medical devices
ASTM	Accelerated aging of sterile barrier system for medical devices
CE or EC	European Conformity
CFG	Certificate for Foreign Governments
CFR	Code Of Federal Regulations
DOC	Declaration of Conformity
EDA	Egyptian Drug Authority
FDA	Food & Drug Administration
FSC or CFS	Free Sale Certificate or Certificate of Free Sale
FSCAs	Field Safety Corrective Actions
FSNs	Field Safety Notices
GMIDN Code	Global Medical Device Nomenclature code
GMP	Good Manufacturing Practice
IFU	Instruction For Use
ISO	International Organization for Standardization
IVD	In Vitro Diagnostic
IVE	In Vito Fertilization
MD	Medical Device
MDR (2017/745)	Medical Device Regulations
MEDDEV	Medical Device Documents
MOH	Ministry of Health
NB	Notified Body
OBL	Own Brand Labeling
OEM	Original Equipment Manufacturer
PMA	Pre-Market Approval
SMH	Summary Of Marketing History
UDI	Unique Device Identification System
UMDN Code	Universal Medical Device Nomenclature System
USP	United States Pharmacopeia