Regulatory Guideline for the Procedures and Rules Organizing the changes done to a Registration license Data of a Medical Device

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1. Introduction:

Whereas the Decree of the President of Egyptian Drug Authority No. (469) of 2021 Regarding the Regulatory Guideline of Introducing a Change on a Registered Medical Device was issued; where the (Article Two) of which stipulates that "The owner of the registration notification of the medical device shall be obligated to inform the Department of Variation in the Central Administration of Medical Devices of any modifications that occur to the medical device.

The modifications referred to herein are divided into: modifications that can be notified of after their implementation, modifications that shall be notified of before their implementation and modifications that shall be notified of and evaluated before their implementation".

Accordingly, it was necessary to issue a regulatory guideline addressing the aforementioned cases and the procedures required to be followed in each case, as well as updating the aforementioned regulatory guideline to comply with the needs of the Egyptian market in, the scientific and practical developments in the field of medical devices and the international standards applied in this regard.

2. Scope of implementation:

The regulatory guideline shall apply to all changes related to registered medical devices in the General Administration of Registration of Medical Devices at the Central Administration of Medical Devices.

3. Definitions:

- **Medical Device:** means 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 Device**: It is the device which is completely manufactured abroad and imported to be placed on the market within the Arab Republic of Egypt.
- **Local Medical Device**: It is the device which is manufactured in facilities inside the Arab Republic of Egypt.
- **Registration Applicant**: It refers to an importing company, local facility or scientific office.
- **The Representative of the Registration Applicant:** He is the representative delegated by the registration applicant to follow up within the Department of Registration.
- **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 the medical device manufactured abroad into the Arab Republic of Egypt.
- **Normal Track**: It is the pathway through which 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**: 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.
- **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 the Reference Countries**:

  United States of America, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.
- **Administration of Medical devices variation:** It is the administration entrusted with making any amendment or correction in the registration, license data, outer or inner labels or the IFU of the medical device.
- **Significant changes in the inner/outer Labeling of a medical device:** They are changes which may require to be stipulated in the medical device's certificates and re-issuance of the registration license. Thus, obtaining an initial number to accept the file.
- **Non-significant changes of the inner/outer labeling of a medical device:** They are changes related to the shape of the inner or outer packaging's labels or content and do not require proofing of them in the medical device's certificates. Nonetheless, they require re-issuance of the registration license and obtaining an initial number to accept the file.

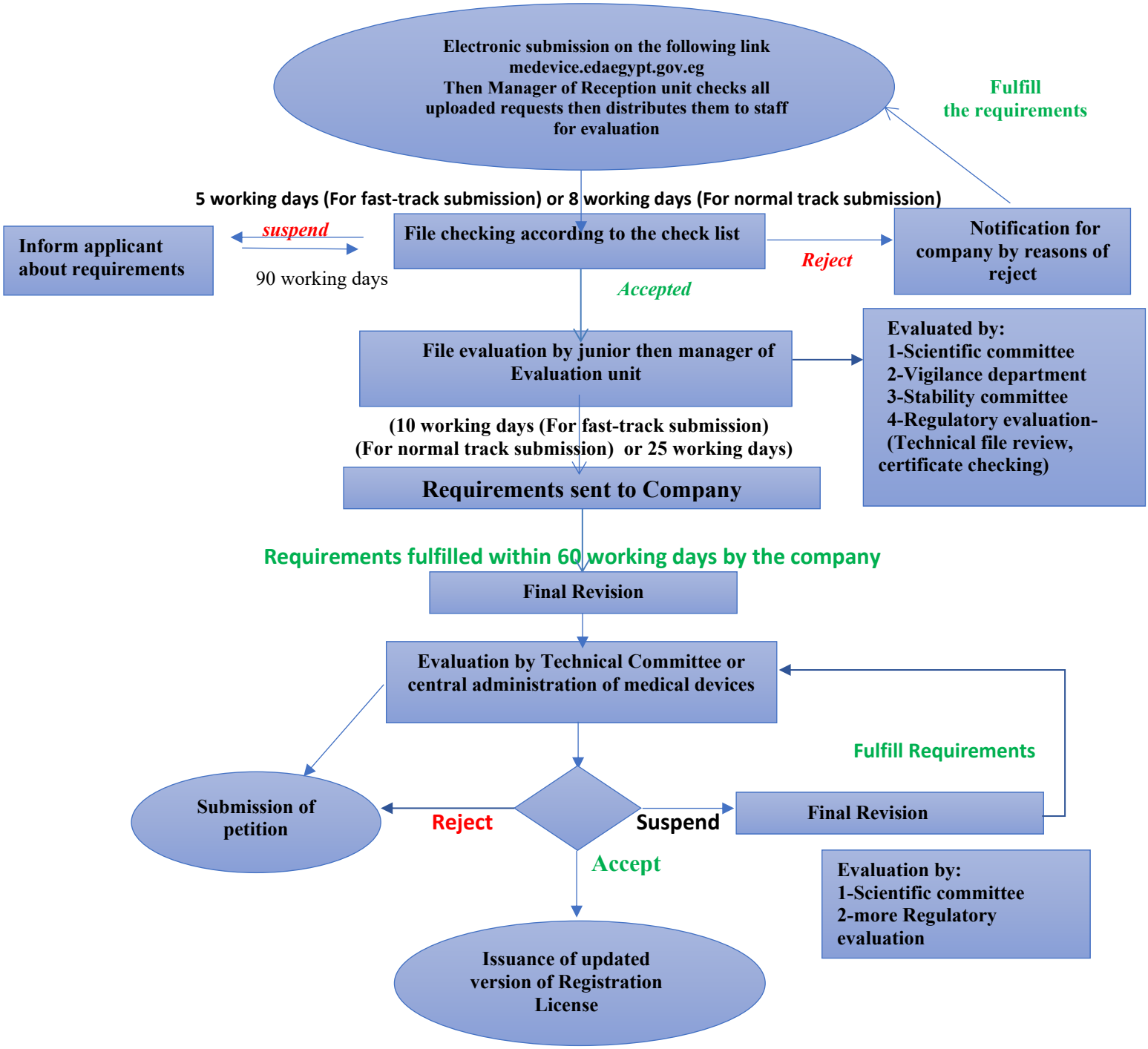
4. Relevant Regulatory Guidelines:

- ✓ Regulatory Guideline of Registration of Locally Manufactured Medical Devices that have International Quality Certificates.
- ✓ Regulatory Guidelines of the Medical Devices Vigilance System.
- ✓ Regulatory Guideline of Procedures and Rules of Obtaining Import Approvals for Medical Devices of all their Kinds.
- ✓ Regulatory Guideline of Using the International Barcodes for the Medical Devices of all their Kinds.
- ✓ Regulatory Guideline of Data of the Labels of the In Vitro Medical Devices and Supplies, the Diagnostic Reagents and Devices and Production Inputs and Components.
- ✓ Regulatory Guideline Concerning Work Procedures of the Central Administration of Licensing of pharmaceutical institutions.
- ✓ Regulatory Guideline Concerning the Procedures and Rules Regulating the Inspection Process of Local Medical Devices Factories.

5.Procedures:

5.1Procedures for applying for a change on a registration license

Flow Chart of Variation of Medical Devices



5.2. Procedures of receiving a variation file:

1- The prescribed service fee shall be paid according to the applied procedures, provided that the concerned device name and the "Administration of Variation in the Central Administration of Medical Devices" shall be indicated to the payment receipt.
2- The applicant shall submit a request on the following electronic platform: medevice.edaegypt.gov.eg
3- The applicant shall receive a response through the platform, within 8 working days for the Normal Track application and 5 working days for the Fast Track application from the date of submitting the request,

The response would be: accepting, refusing or suspending the request until fulfilling the required documents.

- **In case of acceptance**:

The request shall be studied and the applicant will be notified with the required documents whenever necessary.

- **In case of suspending the request until fulfilling the required documents**:

The file shall be suspended in the event of not fulfilling any of the required documents according to the below checklist for a maximum period of 90 working days, after which the request shall be cancelled.
The applicant shall complete the requirements on the electronic platform using the same request number previously submitted.

- **In case of refusal**:

The request shall be rejected in the following cases
1-If any of the device data stated in the applicant's request does not match the receipt or required documents.
2-Or if the request was misaddressed to the administration of medical devices variation.
****A grace period of one year shall be granted for placing the medical device within the Arab Republic of Egypt from the date of acceptance of the variations request.**

5.3. Procedures for evaluating a variation file:

- The file shall be reviewed and the required documents shall be sent on the electronic platform within 25 working days from the date of receiving the file submitted on the Normal Track and 10 working days for the files submitted on the Fast Track.
- The medical device shall be evaluated by the General administration for pharmaceutical vigilance, the specialized scientific committees, or the medical device stability & biocompatibility committee by expressing the scientific opinion on some variations (for the cases included in the below general requirements).

5.4. Procedures of fulfilling the requirements of medical device variation file:

- The required documents of the variation file shall be uploaded on the platform medevice.edaegypt.gov.eg.
- After fulfilling all the documents related to the variation file on the platform, an appointment shall be set for submitting the hard copy file by the applicant's registration representative (*if required)*
- After fulfilling all the requirements, the change shall be evaluated by the Specialized Committee for Registering the Medical Devices or the Central Administration of Medical Devices.
- After obtaining the approval of the Specialized Committee for Registering the Medical Devices or the Central Administration of Medical Devices, an updated version the registration license mentioning the approved change shall be issued.

- **Notes**:

− If the applicant didn't follow up the file for a period of 60 working days, the file shall be archived, the request shall be cancelled and the grace period for placing the medical device in the market shall be suspended.

− if the applicant is willing to re-submit the file, the same previous steps shall be followed.

6. Regulations concerning the submission of a change to a registered medical device:

6.1 Variation types:

Type	Changes	The applied procedure in case of submitting a variation file prior to importation
Do and tell	1. Changing the name of the registration applicant while keeping the same address. 2. Change the address of the applicant) 3. Changing the outer and inner labels data / inner leaflet (if the changes were not significant).	The consignment shall not be seized in the event of implementing one of these modifications, but the applicant shall undertake to **submit the change to** the administration of medical devices variation
Tell and Do	1. Adding / changing / cancelling codes • Adding USP to the surgical -sutures • Cancelling registered codes 2. Request to transfer the place of manufacture (Manufacturing facility/Actual manufacturer) / add a country of origin / add a place of manufacture (Manufacturing facility/Actual manufacturer) for the same legal manufacturer (in the case of adding a non-reference country of origin, a free sale from a reference country shall be submitted). 3. Changing the Medical Device's shelf-life 4. Adding or changing a sterilization method. 5. Changing the registration applicant's name. 6. Changing the name of the manufacturer while keeping the same address. 7. Change of legal manufacturer address. 8. Changing the legal manufacturer or adding a legal manufacturer to the already registered manufacturer (provided that maintaining the actual manufacturer). 9. Change / addition / cancelation of a device packaging 10. Changing the inner and outer labels of a-medical device or inner leaflet IFU (if the changes were significant)	The consignments; that have undergone one of these modifications; shall not be allowed to be placed in the market without applying to the administration of medical devices variation and obtaining an initial acceptance number A grace period of one year shall be granted to the device from the date of acceptance of the file.
Tell, Assess and then Do	1. Change of a device material, substance or a component. 2. Change in the design of a device 3. Change in the intended use of a device (any rephrasing of use indications).	Placing these devices in the market shall be suspended, then the change shall be evaluated to be adjudicated whether it subject to the rules of variation of a medical device or it shall be considered as a new medical device and accordingly a new registration file shall be submitted.

6.2. Applying for the vigilance of a medical devices:

1- A Medical device that has undergone a change should be evaluated by **the General administration for pharmaceutical vigilance** only in the following cases:

- Medical devices classified as AIMD, III and Class IIb on which the following changes are made (adding / changing codes, sterilization method and packaging / changing the shelf life).

2-Manufacturer's commitment about safety of medical devices should be submitted in the following cases:

Medical devices in all their classifications, to which the following changes are made:

- Changing the shelf-life (Extension/Reduction)
- Adding/changing/cancelling codes, packaging, and sterilization method.

3-In the event of applying to submit a variation request to a medical device, the applicant shall be obligated to provide a commitment indicating of the presence of a Medical Device Vigilance System in place and its activities and requirements shall be followed up With the General administration for pharmaceutical vigilance in accordance with the regulatory guidelines of the Medical Device Vigilance System

4- The applicant shall be committed to report any regulatory action concerning the safety of medical device including incidents, recalls, FSNs or FSCAs) that takes place globally or within the Arab Republic of Egypt, in accordance with the time frame and reporting requirements specified in the regulatory guidelines for the Medical Device Vigilance System.

6.3. Variations to be evaluated by the scientific committee of medical devices stability & biocompatibility:

- A stability study file shall be submitted when making changes to a registered medical device in the following cases:

− Adding/Changing medical devices' codes locally manufactured in case of the absence of Free sale certificate mentioning the new codes.

− Change / addition of sterilization method.

− Change / addition of device's primary packaging in case of lacking to a statement from the issuing entity of the quality certificate.

− Changing the storage conditions in the case of lacking to a statement from the issuing entity of the quality certificate.

− Extending the Shelf life of the medical device in the case of lacking to a statement from the Notified body approving the extension of shelf life.

- It is not required to submit a stability study in case of changing the number of units in the registered package / changing in the secondary packaging.
- A biocompatibility study shall be submitted in the case of making changes to a medical device imported from non-reference countries
- The Biocompatibility study shall comply with the following standard (according to which the evaluation will be carried out):

− Biocompatibility study according to ISO 10993.

- The evaluation shall be carried out according to the following standards (or their equivalents if approved by the committee):

− Accelerated Stability study according to ASTM 1980

− Packaging validation according to ISO 11607

6.4 Variations evaluated by the Specialized Scientific Committees:

- The variation file shall be submitted to a scientific committee when undergoing one of the following changes:
  - Adding / changing codes: Refer to the below checklist.
  - Adding a non-reference country of origin.
  - Moving a manufacturing facility to a non-reference country.
  - Making significant changes to the device's IFU.
- **The Scientific Committee shall evaluate the reports issued by the Medical Device Safety Department based on a request of the Safety Department, the Specialized Committee for Registering the Medical Devices or the head of the central administration of medical devices**.)

For surgical sutures imported from non-reference countries:

With regard to the variations related to the USP range of registered sutures, the tensile strength test shall be performed on one of the sizes of the suture subjected to the change. The test result shall be recorded in the reports received from the Central Administration of Drug Control alongside the other test results carried out by the Central Administration of Drug Control, provided that the reports received during proceeding with the procedures of the variation shall be presented to the Specialized Scientific Committee for General Surgery and Plastic Surgery.

For surgical suture imported from reference countries:

With regard to the surgical sutures submitted for a change to the USP range, they shall be subjected to the tensile test after issuing the variations letter re-issuing the registration license for only one size of the surgical suture subject to variation. The test result shall be recorded in the reports received from the Central Administration of Drug Control alongside the other test results carried out by the Central Administration of Drug Control.

For ophthalmic sutures-imported from non-reference countries:

The tensile strength test shall be conducted for all sizes of ophthalmic sutures before and after variations related to the sizes to be added which shall be recorded in the reports received from the Central Administration of Drug Control, in addition to other tests carried out by the aforementioned administration. These reports shall be presented to the Specialized Scientific Committee for Ophthalmology, provided that any incoming consignment shall be sealed and shall not be released except after submitting the aforementioned report of the Authority.

For ophthalmic sutures imported from reference countries:

The tensile strength test shall be conducted for all sizes of ophthalmic sutures after the variations related to the sizes to be added after reissuing the registration license for all sizes required to be added which shall be recorded in the reports received from the Central Administration of Drug Control, in addition to the other tests carried out by the aforementioned administration.

7. Changes related to the artwork data of the outer and inner packaging/ inner leaflet IFU:

7.1 non-Significant changes:

They are changes related to the shape of the outer packaging, for example:

1. Size.
2. Cover color.
3. Order of presenting the data.
4. Logo of the manufacturing company.
5. Add or remove a language on the cover.
6. Adding a graphic showing the method or the purpose of use), provided that it shall not associated with the registration license data.

Required procedure:
The applicant shall not be required to stipulate these modifications in certificates, and it is sufficient to notify the Administration of medical devices variation.

7.2 Significant changes:

They are changes which may require to be stipulated in the medical device certificates and the applicant shall submit a variation file to prove it. These changes are as follows:

1. Any changes to the intended purpose including the limitation of intended purpose
   For example, the medical device is licensed for three indications but the manufacturer decided to market the medical device for only two of those indications.
2. Changes in warnings or precautions:
   Based on manufacturer's post market surveillance, Manufacturer should review warnings and precautions periodically.
3. Changing the storage condition of a medical devices.

Required procedure:
The applicant shall apply to the Administration of Medical devices Variations in order to change/modify the data of the registration license and these modifications shall be stipulated in the certificates.

7.3 Changes that require new-registration submission (shouldn't be submitted to the Administration of Medical devices variations):

1.Labelling changes that reflect new indication
2.Significant changes on indication for use such as:
- Changing a device labeled "single use" only to a device labeled as reusable.
- Changing a device labeled for prescription only to a device labeled for OTC use

3.Changes that include expansion of target population.

8.Case study file:

They are the changes that are not included in the approved variations rules stipulated in the Regulatory Guideline organizing Changes done to a Registered Medical Device.

8.1 Procedures of receiving a case study file

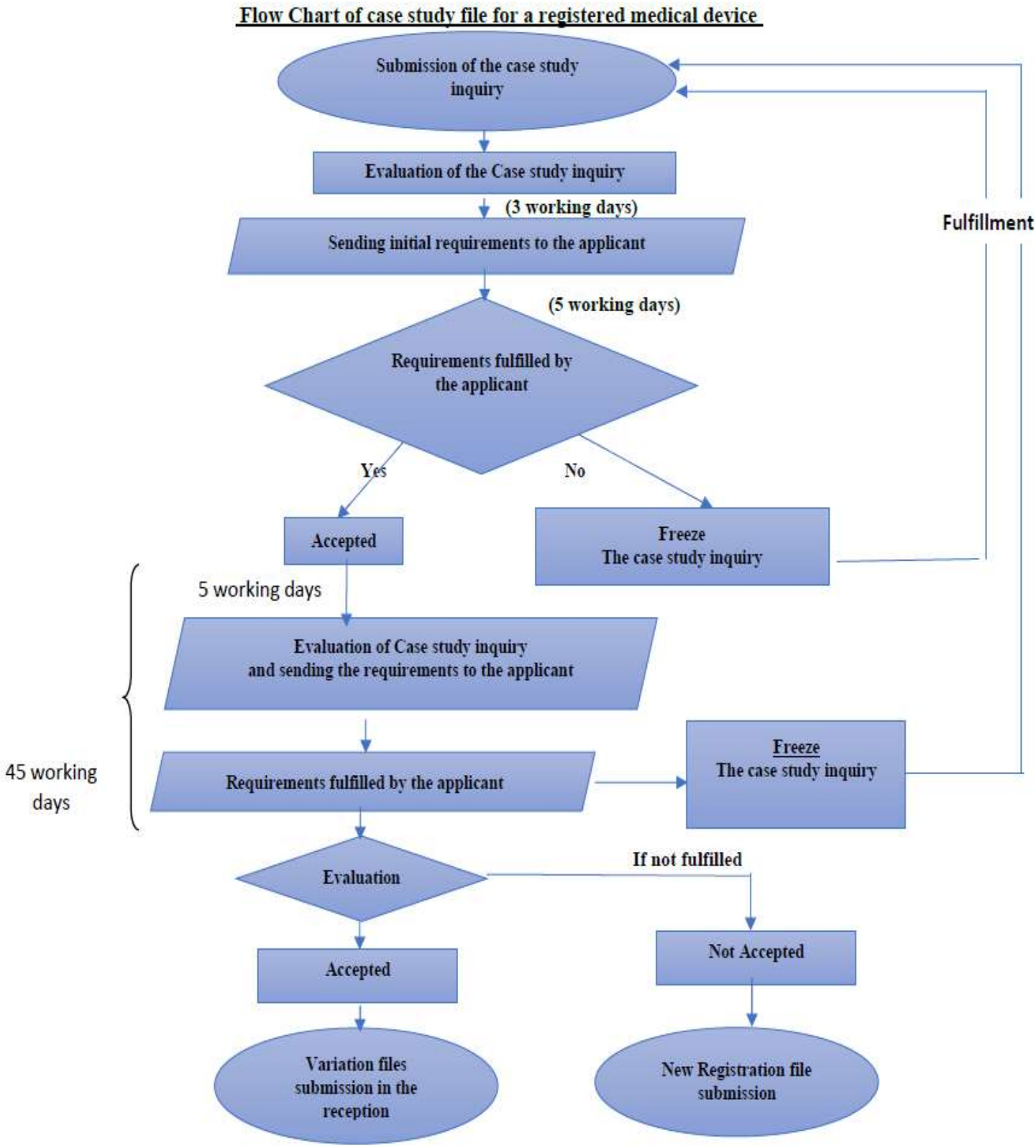
1. A payment receipt (2000 L.E.) shall be submitted provided that the medical device's name would be specified by an EDA registration officer.
2. Submission on the electronic platform MeDevice (medevice.edaegypt.gov.eg)
3. The case study shall be studied and a reply shall be sent through the electronic platform within a maximum of three working days from the date of submitting the application.
4. The required documents necessary to evaluate the case shall be fulfilled within 5 working days, and in case of failure to fulfill them, the application shall be cancelled.
5. In the event of acceptance:

- An initial admission number shall be provided through the platform, evaluating the case study file shall begin.
- After that, a grace period of a maximum of 45 working days shall be granted from the date of accepting the file, the importation of the imported devices or production raw materials in the case of local devices shall be permitted and the case study shall be completed.

8.2 Procedures of evaluating a case study file

1. The file is reviewed and requirements are sent through the platform within 5 working days from the acceptance date.
2. The change is studied and evaluated by the specialized scientific committees or by receiving a notification from the notified bodies within the 45 days grace period.
3. Final Evaluation is done by the central administration of medical devices. In case of acceptance, the applicant shall submit a variation file to the administration of medical devices variation.
4. A case study file is submitted for the changes that are not subject to the variation rules.

8.3 Flow Chart of case study file for a registered medical device



9. Issuing special certificates for export only:

9.1. Mechanism for submitting a request to issue a special certificate for export:

- The local factory shall apply to the Central Administration of Medical Devices.
- An amount of (2000) L.E. shall be paid for technical support service.
- A statement indicating the specifications for export only shall be issued to the company.

9.2. Types of statements issued for export:

✓ Adding codes and trade names for registered medical device intended for export only.

✓ Specify the country/customer in order to issue a statement of codes and names intended for export by the Central Administration of Medical Devices.
The code/trade name added for export only is prohibited to be circulated in the local market.

11. General requirements:

- A period of one year shall be granted for placing the device within the Arab republic of Egypt from the date of the initial acceptance of the variations request.

- It shall be prohibited to make any erasure or alteration of the data of the registration license, otherwise it shall be cancelled.

- It shall not be allowed to submit a request for the Administration of Medical devices Variation and the Administrations of Medical devices Registration (Evaluation, Imported & locally manufactured medical devices) regarding the same registration license, otherwise the variations request shall be cancelled

- In the event of applying for change of both the legal manufacturer and the actual manufacturer of any registered medical devices, it shall be considered a new medical device and the rules of registering the medical device shall apply to it and it shall not undergo to the rules regulating the variations.

- In the event of changing the trade name of a registered medical device, its registration license shall be cancelled, and an application for new-registration shall be submitted

- Regarding the Addition of (Single dose/Multiple dose) to an eye drop:
  This change shall be considered a significant change and an application for new-registration shall be submitted in accordance with the applicable registration procedures.

- Regarding the removal of temperature limit symbol from a registered medical device's labels, it shall be approved in the event of getting an approval of the **notified body**.

- The variation files related to adding sizes, codes or the number of units for syringes without needles used for intravenous, intramuscular or hypodermic injections, shall not be accepted

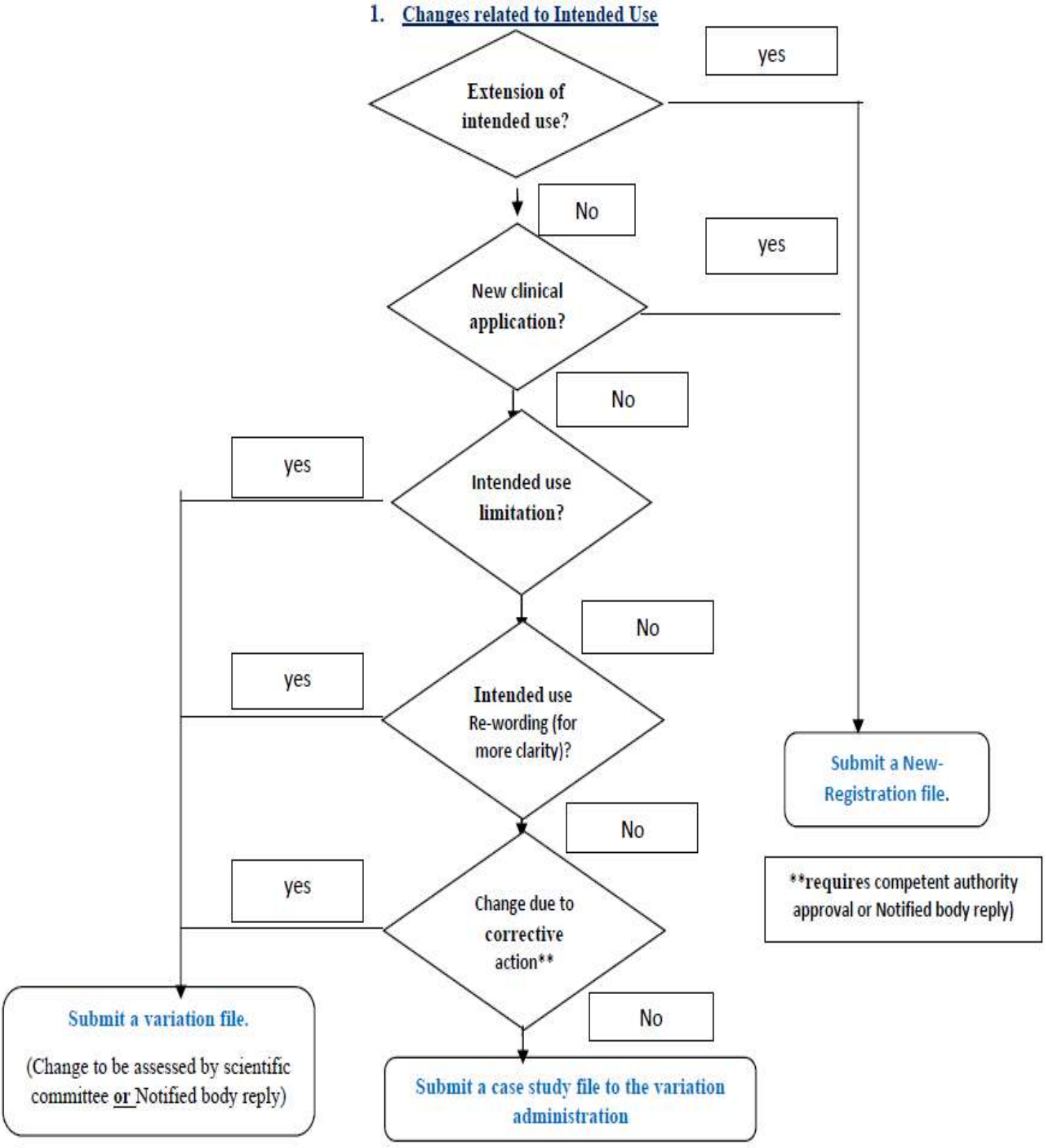
- The variation files related to adding sizes, codes, or number of units/pack for uncuffed Endotracheal Tubes >5mm, shall not be accepted.

- The variation files of any of the Central line catheter or CVC (centrally inserted not peripherally) for the purpose of adding / changing codes / sizes / a package that does not have a pierced syringe / double injection needle / guiding y connector / a passage or a side hole in the needle to enter the guiding wire, shall not be received, provided that the files shall be presented to the Specialized Scientific Committee for Anesthesia and Pain to adjudicate the files in the event of failure to identify whether they fulfill or not the registration requirements

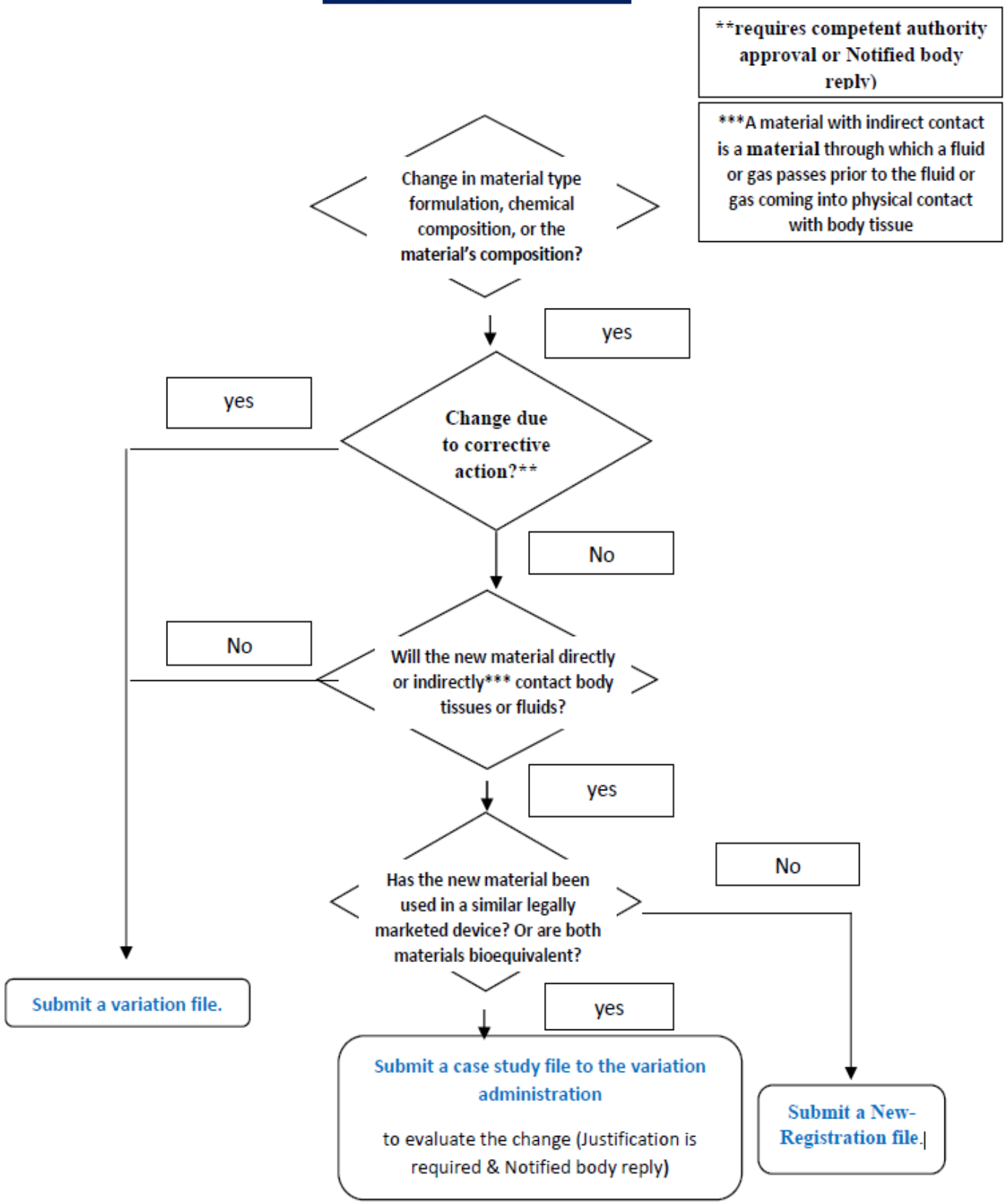
- Applying for a Change in Ophthalmic medical device containing Ectoin shall be accepted provided that they shall not be related to adding concentrations, codes or adding a package (except for changing the number of units/pack).

- Applying for a change in any of the medical device that fall under the Category Urogynecology Surgical Mesh Implants, shall be approved, **provided that the following shall be met**:
  - Obtaining the approval of the Nephrology Specialized Scientific Committee regarding the instructions for use and side effects for all the medical devices in accordance with the recommendations of the TGA.
  - Submitting a Summary of Marketing History for these medical devices and presenting their safety reports to the Specialized Committee for Registering the Medical Devices.

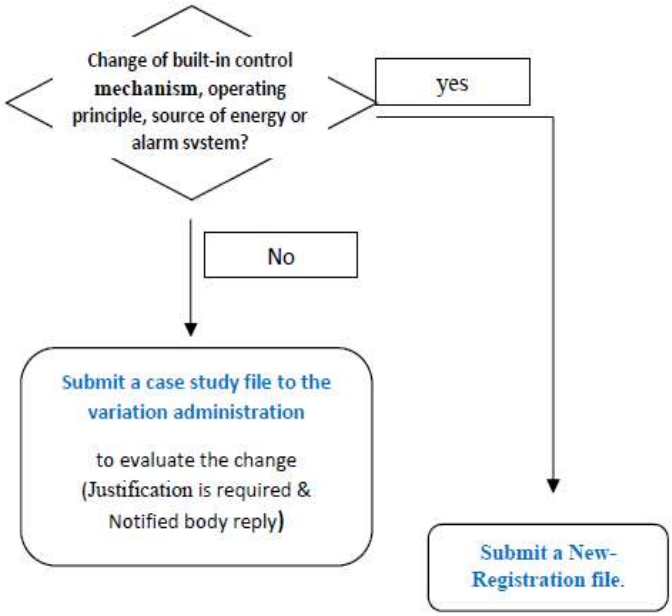
11.A Guiding Flow Chart to determine the pathway of a change (Variation/New Registration/Case study)



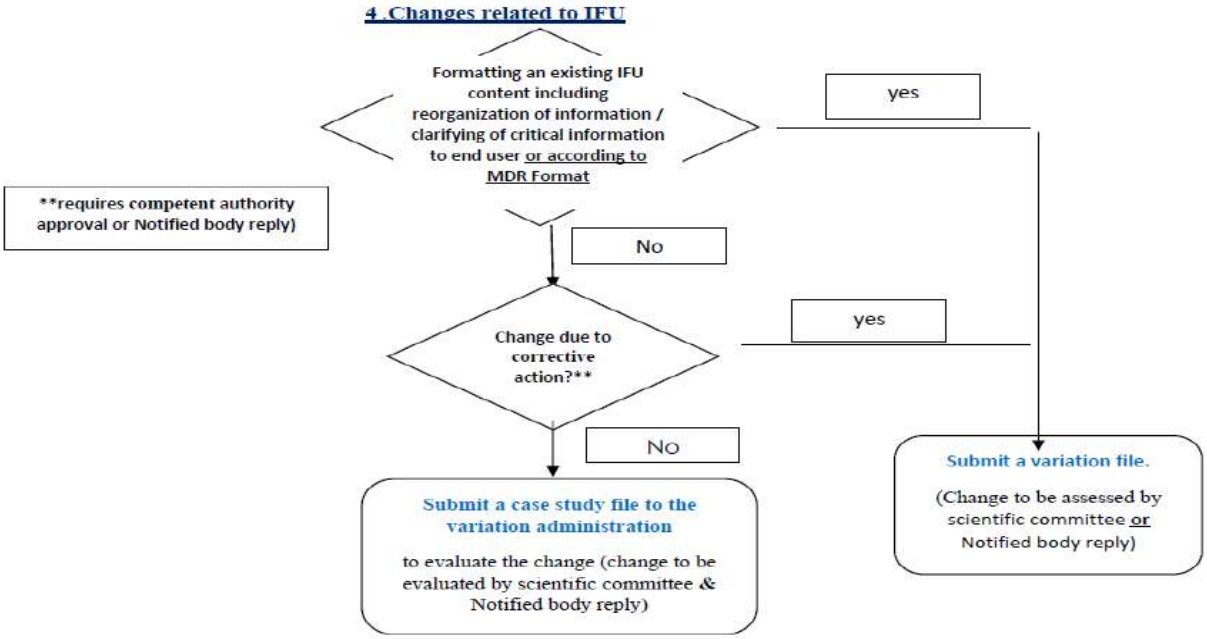
2. Changes related to the materials



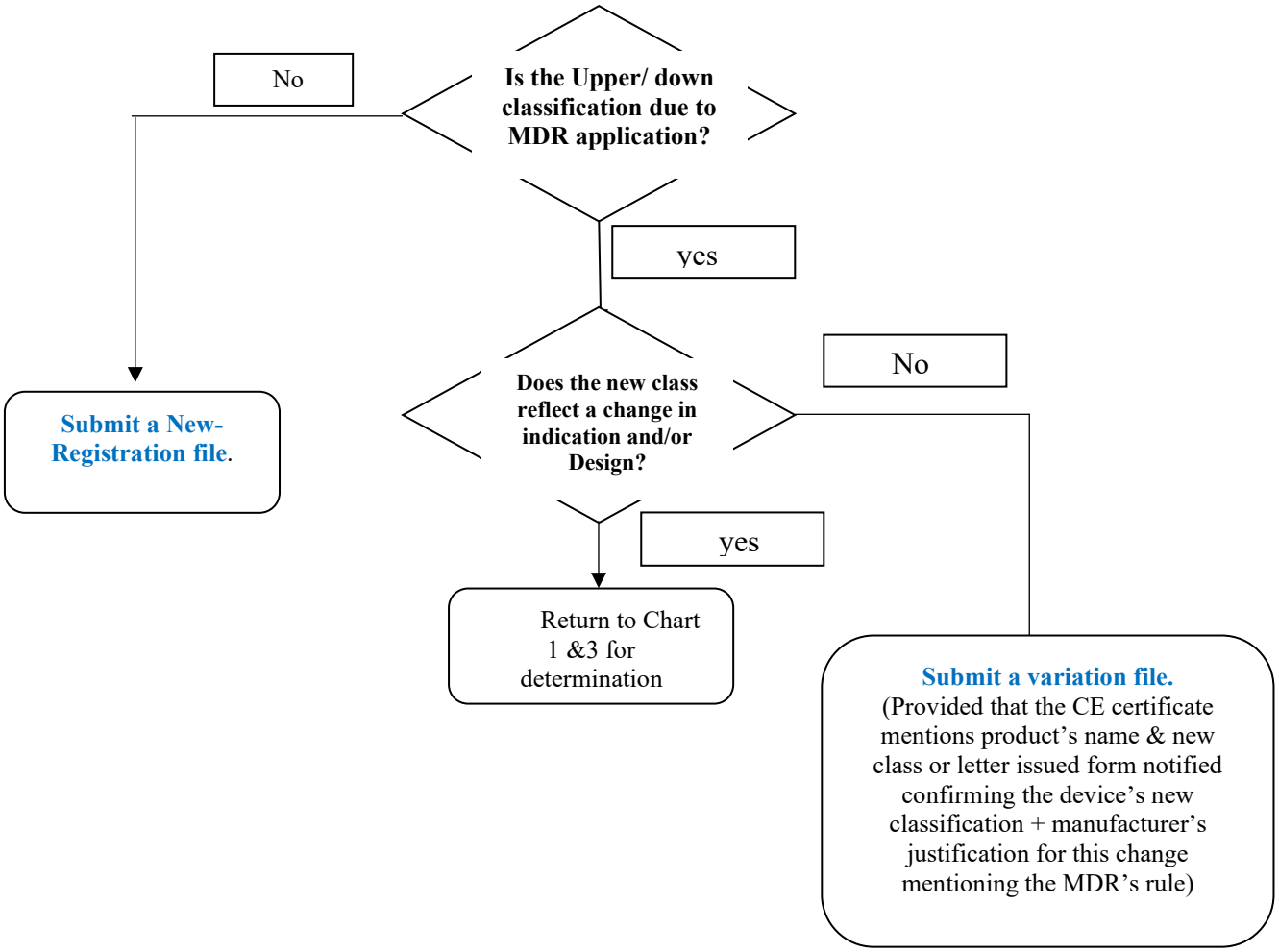
3. Changes related to the Design.



4 .Changes related to IFU



5.Changes related to classification.



12. Appendixes:

Appendix (1) Documents required to make a change in a valid registration license's data

Rule Name	Required Documents
1. A request to add/change codes/cancel codes: changes may be adding new codes, changing or canceling the registered codes. The difference may be in: Gauge, Shape, Diameter, Volume, Suture or Length	1-Payment receipt of the variables service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Quality Certificates: 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 authenticate the quality certificates issued from reference countries (CE, CFG from USFDA, ISO 13485:2016 certificate or EN ISO 13485:2016 FREESALE certificate) by (the Chamber of Commerce and the Egyptian Embassy in the country of origin) which the administration has already verified their authenticity via the authorities that issued these certificates. If these certificates could not be confirmed for authenticity, they shall be submitted after being authenticated by the Chamber of Commerce and the Egyptian Embassy. In the case of not receiving a confirmation by the competent authority/notified body within 3 months from the date of accepting the file, the file shall be archived and it shall be re-submitted after its authentication * **Note**: For the CFG from USFDA, it is not required to be authenticated by the Chamber of Commerce and the Egyptian Embassy in the event that the data of the medical device mentioned therein are verified through the website of FDA CDRH Export certificate validation along with "pre-marketing notification" for medical devices classified as Class II, & FDA CDRH Export certificate validation along with PMA (Premarket Approval) for medical devices classified as Class III. • **Free Sale Certificate** of the medical device which contains the trade name of the medical device, codes or sizes and indicates the legal and actual manufacturer (if any). The certificate shall be issued by the Ministry of Health from 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), or • **CFG issued by USFDA** for the medical device which contains the trade name and codes for the devices and indicates the legal and actual manufacturer (if any). In case of submitting a CFG from USFDA, a CE certificate is not required. ISO13485 certificate is not required if the FDA certificate mentions:" the plant at that time appeared to be in compliance with current good manufacturing practice requirements". • **The CE certificate** for the finished product with all its components, accessories and models issued by the (Notified body) taking into account the Annex to the certificate) according to the classification of the product. In the event that the medical device contains a bovine substance, the CE certificate shall 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).

** CE certification is not required to be submitted for Class I Non-Sterile medical device.

- **ISO 13485: 2016 certificate or EN ISO 13485: 2016** certificate issued by an internationally accredited certification body, provided that the certificate shall cover the product category.
- **Declaration of conformity certificate**: The certificate shall be stamped and signed by the legal manufacturer, and contains the trade name of the medical devices; the registered and new codes or sizes, and kit/ set contents in the case of kit/ set, provided that the following shall be indicated in the certificate:

  The manufacturer's responsibility for the product's quality, the notified body, the CE certificate number, the indication of use, the classification and the actual manufacturer, if any.

5-The original registration license

6-A Manufacturer's letter of no change stating that there is no change in the product in terms of raw materials, shelf life, packaging, sterilization, analysis, stability study, inner and outer labels, classification, indications, GMDN codes, provided that the difference between the registered and new codes is may be a difference in: Gauge, shape, diameter, volume or suture (no of Strands).

* A Justification for the changes to be done shall be stated by the Manufacturer

7-A letter issued by the legal manufacturer that includes the following table:

Factors	Registered codes	New codes
Do the devices have the same classification?		
Do they have the same GMDN Codes?		
Do they have the same intended use?		
Do the devices Operate or Function in the same way?		
Physical design and construction the same or very similar?		
Are the devices of the same Material(s)?		
Are the risk profiles for each of the devices the same?		

8-The change shall be evaluated by the Specialized Committee for Registering the Medical Devices or by the head of the Central Administration of Medical devices in the event of fulfilling the previous documents.

9-For the code changes that are not related to Gauge, Shape, Diameter, Volume or Suture (no. of Strands), the change shall be evaluated first by the specialized scientific committee. The required materials are (a file to be presented to the specialized scientific committee + submitting a sample). Then the change shall be evaluated by the Specialized Committee for Registering the Medical Devices or to the Head of the Central Administration of Medical devices

10-Submitting inner & outer label & IFU for the new codes, signed and stamped by the manufacturer.

	For surgical sutures ~~-~~imported from non-reference countries: With regard to the variations related to the USP range of the registered sutures, the tensile strength test shall be performed on one of the sizes of the sutures subjected to variation ~~-~~The test result shall be recorded in the reports received from the Central Administration of Drug Control alongside the other test results carried out by the Central Administration of Drug Control, provided that the reports received during proceeding with the procedures of the modifications shall be presented to the Specialized Scientific Committee for General Surgery and Plastic Surgery. **For surgical sutures imported from reference countries**: With regard to the surgical sutures submitted for variations related to the USP range, they shall be subjected to the tensile strength test after issuing the variations letter for only one size of the surgical sutures subject to variation. The test result shall be recorded in the reports received from the Central Administration of Drug Control alongside the other test results carried out by the Central Administration of Drug Control. **For ophthalmic sutures imported from non-reference countries**: The tensile strength test shall be conducted for all sizes of ophthalmic sutures after both the initial acceptance and the final acceptance of the submitted variation if it is related to addition of sizes, the tests shall be recorded in the reports received from the Central Administration of Drug Control, in addition to other tests carried out by the aforementioned administration. These reports shall be presented to the Specialized Scientific Committee for ophthalmology, provided that any incoming consignment shall be seized and shall not be released until the submission of the aforementioned Authority report. **For ophthalmic sutures imported from reference countries**: The tensile strength test shall be conducted for all sizes of ophthalmic sutures after ~~/~~ the final acceptance of sizes addition as well as the issuance of the variations letter for all sizes to be added, the test shall be recorded in the reports received from the Central Administration of Drug Control, in addition to the other tests carried out by the aforementioned Administration. **In the event that the manufacturer would like to cancel codes mentioned in the registration license**: a file shall be submitted includes the aforementioned documents in codes addition/change, in addition to a Justification for the code cancellation signed and stamped by the legal manufacturer. **In the event of adding/changing codes for locally manufactured medical devices:** A stability study or a Free sale certificate should be submitted.
2. Request to change the manufacturing site / add a country of origin / add a manufacturing facility to the same legal	1-Payment receipt of the variables service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license

manufacturer (in case of adding a non-reference country of origin, a free sale certificate from a reference country shall be submitted)	3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Quality and free sale certificates *(CE & ISO certificate, free sale or USFDA, Declaration of conformity) 5-The original registration license 6-A relationship between the manufacturer's affiliates authenticated by the Chamber of Commerce. & Egyptian ambassy 7- A Manufacturer's letter of no change stating that there is no change in the product in terms of the raw materials, shelf life, packaging, sterilization, analysis, stability study of the medical device, but it is only limited to the manufacturing site. 8-Inner and outer label and IFU for the new facility. 9-Submitting a scientific committee file + sample in case of adding a non-reference country of origin.
3. Request to change the shelf-life	1-Payment receipt of the variables service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4- **In the event of shelf-life extension, the following is required:** A. A Manufacturer's statement declaring the extension, the Justification for modifying and the reason for changing the shelf life. The document should be original signed and stamped by the legal manufacturer B. Addressing the **Notified Body** concerned with issuing the quality certificate of the medical device to verify the shelf-life extension or submitting a stability study to be evaluated by medical device stability & biocompatibility committee 5-**In the event of shelf-life reduction, the following shall be applied:** Submitting an original, signed and stamped statement by the legal manufacturer/ manufacturer declaring the shelf-life reduction as well as reasons and justification for this reduction. The shelf-life reduction shall be approved by the Specialized Committee for Registering the Medical Devices. **6-In the event of correcting the shelf-life as a result of a mistake in the shelf-life certificate provided by the manufacturer:** the Notified Body concerned with issuing quality certificate for the medical device, shall be addressed to verify the shelf-life of the medical device or a stability study shall be submitted to be evaluated to the medical device stability & biocompatibility committee. Also, the manufacturer shall submit a justification for correcting the shelf-life.

4. Request to add/change the sterilization method	1-Payment receipt of the variables service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Quality and free sale certificates: CE & ISO certificate, free sale or USFDA, Declaration of conformity. 5-The original registration license. 6-A Manufacturer's letter of no change clarifying the change to be done & stating that there is no change in the product in terms of: raw materials, shelf life, packaging, analysis, inner and outer labels, classification, indications, GMDN code. 7-Signed and stamped performance data for new sterilization method/s. 8-Signed and stamped comparison study between old & new sterilization methods. 9-Inner & outer label for New Sterilization Methods signed and stamped by the manufacturer. 10-Stability study for the new sterilization method to be evaluated by the medical device stability & biocompatibility committee, then the Specialized Committee for Registering the Medical Devices-or the Central Administration of Medical Devices. 11-The file to be evaluated by the medical device stability & biocompatibility committee shall include the following documents: A. Application. B. Sterilization validation report. C. Stability study for the new sterilization method.
5. Changing the registration applicant	**A) In the event of the possession of the original registration license by the new applicant:** 1-Payment receipt of the variables service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4- The original of the valid registration license. 5- A waiver from the old applicant approved by the applicant's Chairman of the Board of Directors along with the bank or EDA's legal administration attestation of the chairman's signature.

	6-Medical devices Importers' record license issued by the Central Administration of Licensing of pharmaceutical institutions for the new applicant, that states the name of the manufacturer and specifies the products subjected to the jurisdiction of the agency. Or An Authenticated Authorization letter for the applicant to register the medical device. The letter shall indicate the trade name of the medical device, the name and address of the applicant and shall be issued by either: a. The legal manufacturer or whosever is authorized by the legal manufacturer under an authenticated relationship. b. The Mother company or whosever it authorizes under an authenticated relationship (showing the parent company, the legal manufacturer and the entity responsible for issuing the registration authorization as well as indicating of the name and address of each of them) and the renewed commercial register of the importing company. 7-A termination letter of the agreement with the former applicant issued by the legal manufacturer and authenticated by the Chamber of Commerce and the embassy. **In the event of failure to submit any of the aforementioned documents, the new applicant shall submit an application for new registration, provided that he shall be granted a one-year grace period to import the medical device from the date of acceptance of the file by the Administration of Medical Devices Evaluation. The grace period is being granted considering that the medical device is already placed in the Egyptian markets and to prevent any difficulties while using the devices. **B) In the event of transferring the registration license from an agent or distributor to a scientific office (for imported medical devices)**: 1-Payment receipt of the variables service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4- The original of the valid registration license. 5-The scientific office license issued by the Egyptian Drug Authority indicating the name of the Manufacturer. In the event that the mother company is mentioned in the scientific office license, the scientific office shall submit a letter explaining the relationship between the entity mentioned in the scientific office license and the legal manufacturer, provided that this relation shall be authenticated by the Chamber of Commerce and the Egyptian embassy in the country of the origin. 6-Authorization letter issued from the manufacturer for the scientific office to register the medical devices provided that the letter shall indicate the names of the devices that are undergoing this change whose registration licenses are required to be transferred and that the letter shall be authenticated by the Chamber of Commerce and the Egyptian embassy in the country of origin.

	7- A termination letter of the agreement with the former applicant issued by the legal manufacturer and authenticated by the Chamber of Commerce and the embassy. 8- A waiver from the old applicant approved by the applicant's Chairman of the Board of Directors along with the bank or EDA's legal administration attestation of the chairman's signature. 9- An approval letter of allowing the scientific office to register medical devices for the benefit of the legal manufacturer (issued by the Administration of Evaluation). **C) In the event of transferring the registration license from an agent or distributor to an affiliate scientific office:** 1-Payment receipt of the variables service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4- The original of the valid registration license. 5-The scientific office license issued by the Egyptian Drug Authority. 6- Submitting a letter of authorization/contract of agreement/agreement to provide registration services, whether between the scientific office and the manufacturer, or the old applicant to which the scientific office is affiliated and the manufacturer indicated in the scientific office's license. This letter shall explain the capability of the scientific office to carry out the registrations in Egypt, provided that the letter shall specify the devices names for which the registration license is required to be transferred or all of the devices and it shall be authenticated by the Chamber of Commerce and the Egyptian Embassy in the country of origin. 7-Proofing of the contractual relationship between the scientific office and the old applicant to which the scientific office is affiliated. It is permissible to submit an Authorization letter/ Authorization agreement/ Authorization Services, provided that the letter shall indicate devices names for which the registration licenses are required to be transferred or all of the devices or all the devices. The letter shall be approved by the bank or the EDA's legal administration attestation of the chairman's signature. 8- An approval letter of allowing the scientific office to register medical devices for the benefit of the legal manufacturer (issued by the Administration of Evaluation).
6. Changing the name of the applicant while keeping the same address	1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license

	3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Applicant's Medical devices Importer's record license issued by the Central Administration of Licensing of pharmaceutical institutions for the new applicant, that states the name of the manufacturer and specifies the products subjected to the jurisdiction of the agreement. 5-The renewed commercial register of the applicant. 6-The original and valid registration license.
7. Changing the address of the applicant	1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-A Medical devices Importer's record license issued by the Central Administration of Licensing of pharmaceutical institutions for the new applicant, that states the name of the manufacturer and specifies the products subjected to the jurisdiction of the agreement. 5-The renewed commercial register of the applicant. 6- Original valid registration license.
8. Changing the name of the manufacturer while keeping the same address	1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Quality and free sale certificates mentioning manufacturer's new name: *(CE & ISO certificate, free sale or USFDA, Declaration of conformity). 5-A Manufacturer's letter of no change stating the following: * The manufacturer is changing its name (indicating the change from the old name and address to the new name and address). * The trade names of the medical devices.

	* Stating that there will be no change in terms of the raw materials, shelf life, packaging, sterilization, analysis, stability study and the trade name of the medical device (i.e., any item related to the technical file submitted for registration), and the change is only limited to the manufacturer's name. 6-Applicant's Importer record license mentioning the new manufacturer's name. 7-Valid original registration license. 8-Submitting a copy of the inner/outer label of the packages with the new manufacturer's name signed and stamped by the manufacturer.
9. Changing the address of the legal manufacturer	1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Quality and free sale certificates (CE & ISO certificate, free sale or USFDA, Declaration of conformity) with the new address of the legal manufacturer. 5-A Manufacturer's letter of no change stating the following: * The change in legal manufacturer's address clarifying the old and the new address as well as the actual manufacturer and its address. * The trade names of medical devices. * Stating that there will be no change in terms of the raw materials, shelf life, packaging, sterilization, analysis, stability study, the trade name, indications and the purpose of classification of the medical device, but it is only limited to the address of the legal manufacturer. 6-Valid original registration license. 7-The inner / outer label for the medical device with the new legal manufacturer address; signed and stamped by the legal manufacturer.
10. Changing or adding a legal manufacturer (provided that, there is no change in the actual manufacturer)	1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023

	4-Quality and free sale certificates (CE & ISO certificate, free sale or USFDA, Declaration of conformity) mentioning the new legal manufacturer. 5-A Letter of no change issued by the legal manufacturer stating the following: a. Adding / changing a legal manufacturer along with stating its name and address. b. Indicating the trade names of the medical devices. c. Stating that there will be no change in terms of the raw materials, shelf life, packaging, sterilization, analysis, stability study, trade name, classification and GMDN code (i.e., any item related to the technical file submitted for registration) of the medical device, but the change is only limited to adding / changing of the legal manufacturer. 6-Medical devices Importer's record license mentioning the new legal manufacturer. 7-Valid original registration license. 8-The inner / outer label for packages with the new legal manufacturer signed and stamped by the new legal manufacturer. 9-Relationship letter between the manufacturer's affiliates authenticated by the Chamber of Commerce. **General rule**: In the event of submitting a request to change both the legal manufacturer and the actual manufacturer of any registered medical device, it shall be considered a new medical device and it shall undergo to the rules of registering the medical device while the variations rules shall not be applied.
11. Changing/-adding, or canceling of a device packaging	1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Quality and free sale certificates (CE & ISO certificate, free sale or USFDA, Declaration of conformity). 5-Valid original registration license. 6-A Manufacturer's letter of no change stating that there will be no change in terms of the raw materials, shelf life, packaging, sterilization, analysis, stability study, inner and outer labels, classification, indications, GMDN code of the medical device. The letter should clarify the changes done to the device's packaging and no. of units/pack. In case of submitting a request to cancel a package, the reason for canceling the package shall be indicated). 7-New Packaging certificate mentioning the packaging material and packed quantity. 8-Submitting an inner & outer label signed & stamped by the manufacturer. 9-Submitting a stability study issued, signed and stamped by the manufacturer.

	* The stability study submitted by the manufacturer for the new packaging shall be evaluated by the medical device stability & biocompatibility committee then by the Specialized Committee for Registering the Medical Devices * The sterilization validation report shall not be requested in the case of changing / adding a package for non-sterile medical device according to the decision of the Technical Committee for the Registration of Medical Device on Jan 3rd, 2013. * The stability study shall not be requested in the case of changing the number of units in the registered package / change in the secondary packaging / A change in the dimensions of the package (For the packaging dimensions change; a notification shall be received from the notified body approving the change). **In the event of changing the packaging of an accessory of a registered medical device**: Stability studies are not required to be evaluated by the medical device stability & biocompatibility committee provided that the accessory is packed in the same primary package of the final product that has not been modified from the package description stated in the registration license.
12. Changing of the artwork data of the outer and inner packaging / inner leaflet IFU	**Non-significant modifications**: The applicant/manufacturer shall not be committed to indicate these changes in the certificates, and it is sufficient to notify the Administration of medical devices-registration in the General Administration of Medical device Registration. Central Administration for Inspection on pharmaceutical institutions shall be notified with these changes via the shared database between the Administration of medical devices-registration and Central Administration for Inspection on pharmaceutical institutions. 1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license 3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Lay out for the new labels or IFU from legal manufacturer signed and stamped. 5-A comparison between the old labels / IFU and the new labels /IFU. **Significant modifications**: They are changes that may require to indicate it in the certificates of the medical device. 1-Payment receipt of the variation service. 2-The original delegation for the applicant's representative approved by the applicant's chairman of the Board of Directors along with the bank or the EDA's legal administration attestation of the chairman's signature describing the representative's responsibilities to act on behalf of the applicant with the general administration of medical devices' registration and to have the right to collect the original registration license

	3-Applicant's commitment to adhere to medical devices' vigilance system in accordance with the Egyptian vigilance center's announcement on 01/08/2023 4-Quality and Free sale certificates (CE & ISO certificate, free sale or USFDA, Declaration of conformity). 5-A Manufacturer's letter of no change stating the required modifications and its justifications and indicating that there will be no change in terms of the raw materials, shelf life, packaging, sterilization, analysis, stability study, inner and outer labels, classification, indications, GMDN code of the medical device. The type of change shall be indicated. 6-Two original copies of the art work of the inner / outer labels or the modified IFU, stamped and signed by the legal manufacturer. An original copy shall be attached to the letter addressing to the Central Administration for Inspection on pharmaceutical institutions to inform it of the modification. 7-The required modification shall be evaluated by the specialized scientific committee, and then it shall be evaluated to the Specialized Committee for Registering the Medical Devices. 8- In case of changing the storage conditions, a complete stability study shall be submitted containing: * Protocol of stability study. * Storage conditions (Temperature, for how long, no. of samples). * Evaluation of tests done, * Calculation of shelf life, * Conclusion for the study, The study shall be evaluated by the Specialized Scientific Committee for Stability Studies, otherwise a statement from the Notified body.

Appendix (2)

Quality & Free sale Certificates of registered medical devices required to be originally authenticated)

1- According to Japan's Regulations:

Required documents	Class
1-Declaration of Conformity according to Japanese regulations. **2-Free sale certificate (Issuance authority MHLW).** **3-Certificate of Quality management system conformity (kijun tekigoshou) (In conformity with ordinance 169)** Or (MDSAP) Issued to MAH and foreign manufacturer ("if present") (if applicable according to JMDN) (Issuance authority MHLW or RCB).	**Class I**
1-Declaration of Conformity according to Japanese regulations. **2-Free sale certificate (Issuance authority MHLW).** **3-Certificate of conformity Issuance authority registered certification body (RCB)** **4- Certificate of Quality management system conformity (kijun tekigoshou)(In** conformity with ordinance 169) Or (MDSAP) Issued to Market authorization holder and foreign manufacturer "if present") for all classes and class I devices (if applicable according to JMDN) (Issuance authority MHLW or RCB).	**Class II** **Class III**
1-Declaration of Conformity according to Japanese regulations. **2-Free sale certificate (Issuance authority MHLW).** **3- Certificate of Quality management system conformity (kijun tekigoshou)(In** conformity with ordinance 169) Or (MDSAP) Issued to Market authorization holder and foreign manufacturer "if present") for all classes and class I devices (if applicable according to JMDN) (Issuance authority MHLW or RCB).	**Class IV**

2- According to the United Kingdom's (England-Wales-Scotland) regulations (not necessarily sold inside the European union):

Certificates	Class
1-**DOC** certificate mentioning (UK MDR 2002) & classification. **2- Free Sale** certificate: • Imported Medical devices: Free sale certificate from the country of origin or any reference country. • Local Medical devices: Free Sale certificate from any reference country or submitting a stability study to be evaluated by the scientific committee of stability and biocompatibility.	**Class I non-sterile dosage form**
1-**DOC** certificate mentioning (UK MDR 2002) & classification. **2- Free Sale** certificate: • Imported Medical devices: Free sale certificate from the country of origin or any reference country. • Local Medical devices: Free Sale certificate from any reference country or submitting a stability study to be evaluated by the scientific committee of stability and biocompatibility. **3-** ISO 13485:2016 certificate. **4-** (UKCA) United Kingdom Conformity Assessment certificate.	**Class Is, IIa , IIb, III.**

3-According to Canada's regulations:

Required documents	Class
1-Declaration letter mentions full medical device list submitted to the Egyptian health authority **2- DOC according to Canadian regulation mention the classification** **3-Manufacturer certificate to cover export of medical devices (= FSC) issued** from: the (HPFBI), Health Canada 4-**Medical device establishment license**	**Class I**
1-**Declaration letter mentions full medical device list submitted to the** Egyptian health authority **2-Medical device active license** (In case medical device active license is issued for medical device family, medical device group, or medical device group family) N.B: the declaration letter will be sent to the health Canada to confirm that the license covers the whole medical device list **3-DOC according Canadian regulation mention the classification** **4-Manufacturer certificate to cover export of medical devices (= Free sale)** issued from: The Health Products and Food Branch Inspectorate (HPFBI), Health Canada **5-MDSAP certificate.**	**Class II, III, IV**

[COMPANY NAME]

(Date)

Appendix (3): Manufacturer's Commitment About Safety of Medical Devices

Declaration (1)

For MDs Class I and II a

Dear Head of Central Administration of Medical Devices,

Dear General Manager of General Administration of Medical Devices Registration,

For the following medical device applied for new registration/ re-registration/variation of registration license 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 recall, FSNs, or FSCAs) raised after the application for registration/ re-registration/ 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 " 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 (PS Rs), or regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) to the "Medical Device Safety Department " 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 ".

Signature

title

[COMPANY NAME]

(Date)

MANUFACTURER'S COMMITMENT. ABOUT SAFETY OF MEDICAL DEVICES

[Declaration (2)

For Class IIb, III, and (I, IIa with Regulatory Actions)

Dear Head of Central Administration of Medical Devices,

Dear General Manager of General Administration of Medical Devices Registration,

For the following medical device applied for new registration/re-registration/variation of registration license 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/re-registration /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 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 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 ".

Signature

Title

Date

Appendix (4) Documents required for the case study file

1- An application on applicant's letterheads explaining the change in detail.
2- A full copy of the registration License (and variation supplementary, if any).
3- A copy of the free sale and quality certificates (Free Sale + CE + ISO13485:2016 or CFG from USFDA + ISO 13485:2016).
4- A copy of the Declaration of conformity.
5- A copy of the letter approved by the manufacturer stating that there is no change in the product in terms of raw materials, shelf life, packaging and packing, sterilization, analysis, stability study, inner and outer packaging data, classification, purpose of use, GMDN code and the required modification shall be explained in detail.

** **Important note**: The rest of the required documents shall be determined according to the change to be implemented

9. Glossary of abbreviations:

Acronym	Definition
EDA	Egyptian Drug Authority (هيئة الدواء المصرية)
MD	Medical Device (مستلزم طبى)
AIMD	Active Implantable Medical Device (مستلزم طبي يزرع داخل الجسم)
ISO	International Organization for Standardization (المنظمة الدولية للمقاييس)
CE or EC	European Conformity (المطابقة الأوروبية)
FDA	Food & Drug Administration (منظمة الغذاء والدواء الأمريكية)
CFG	Certificate for Foreign Governments (شهادة للحكومات الأجنبية)
FSC or CFS	Free Sale Certificate or Certificate Of Free Sale (شهادة التداول الحر)
NB	Notified Body (جهة إصدار شهادات الجودة)
DOC	Declaration Of Conformity (إعلان المطابقة)
IFU	Instruction For Use (تعليمات الاستخدام)
GMDN Code	Global Medical Device Nomenclature (المعيار العالمي لتسمية المستلزمات الطبية) code
REF	Reference (مرجع)
FSNs	Field Safety Notices (إشعار السلامة الميدانية)
GMP	Good Manufacturing Practice (ممارسات تصنيعية جيدة)
PMA	Pre-Market Approval (اعتماد ما قبل التسويق)
USP	United States Pharmacopeia
ASTM	Accelerated aging of sterile barrier system for medical devices
CE-Marking	It is an administrative mark indicating that this medical device complies with health and safety standards for products circulated in the European Economic Area.

10. Versions:

Places of Amendments	Issue date	version
	28/10/2021	**First**
Addition of: - flow chart to determine the type of change (variables - new registration - case study file) - Changes in variation rules - case study file - Issuance of special export certificates - supplementary letter to free sale and quality certificates for registered medical devices	11/12/2023	**Second**
The name of the Central Administration of Operations has been updated to become the Central Administration for Inspection on pharmaceutical institutions or the Central Administration of Licensing of pharmaceutical institutions whenever they are mentioned in the guideline, depending on the specialization.	01/09/2025	**Third**