

## Medical Device Regulatory Requirements for Egypt

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### **Summary**

The Egyptian Ministry of Health (MOH) is responsible for the registration and approval of medical devices in Egypt. It does this through the Drug Policy and Planning Center (DPPC) and the Central Administration of Pharmaceutical Affairs (CAPA). Since January 2005, the MOH started to apply stricter rules regarding the registration requirements of medical devices in Egypt. These rules were designed to reduce the number of forged certificates submitted to the registration department of the MOH. Official sources report that, as a result, the number of invalid applications submitted to the MOH has decreased and the level of rejection is falling resulting in only reputable high-quality products being marketed in Egypt. The new regulations have led to the early detection and cancellation of forged CE or FDA certificates, before they reach the medical device committee, giving reviewers more time to deal with genuine submissions and thus a relatively faster approval lead time. Furthermore, some companies have reportedly stopped working in the medical device field following the discovery of forged certificates.

The following characteristics summarize the medical device registration process in Egypt:

- Imported medical products must be registered with the MOH.
- Egypt has adopted the European Risk Classification System for medical devices (Class I, IIa, IIb, and III).
- Devices other than non-sterile Class I require proof they are freely sold in a country.
- A Free Sale certificate, and a CE Mark or FDA Approval are required.
- Class III applications must include the original technical file.
- Locally manufactured products must be clearly labeled as such.
- Applications for complex medical equipment may be diverted to a special committee.
- Importation of used or refurbished medical devices is not allowed without prior approval of the MOH.

The following details the steps involved in registering a medical device in Egypt, with emphasis on the requirements.

## **Regulatory System**

The MOH is responsible for the registration and approval of medical devices in Egypt. It does this through the Drug Policy and Planning Center (DPPC) and the Central Administration of Pharmaceutical Affairs (CAPA). The DPPC controls and sets the strategic rules for drug policy but it also regulates the importation and manufacture of medical devices and instruments. It controls the registration of medical devices through a Specialized Committee for Study of Manufactured and Imported Medical Devices and Equipment. This committee comprises leading medical professors (approximately 10) from the specialties of ophthalmology, orthopedics, surgery and cardiology, as well as professors in medical engineering. The committee also includes pharmacist managers from CAPA, DPPC and the National Organization for Drug Control and Research (NODCAR).

This committee is responsible for reviewing and approving applications for the manufacture or importation of medical devices and equipment in Egypt. Applicants may be importing companies, manufacturing companies, physicians or individuals. The committee evaluates an application in light of the existing status of the device or equipment in question and whether there is a real need and benefit for Egyptian patients. It then issues a decision regarding the application before the equipment is released from customs or manufactured. As explained below, additional evaluation by another body is often required.

CAPA is responsible for registering and issuing final marketing approval for Class III medical devices.

## **Registration Procedures**

Egypt has adopted the definition and classification of medical devices according to European Medical Devices Directive (Directive 93/42/EEC). Applicants should therefore classify their products as Class I (low risk), Class IIa or Class IIb (medium risk), or Class III (high risk). The class and type of device will determine which procedure will apply:

- Class I, Class IIa and Class IIb devices are registered at the DPPC where an import approval or manufacturing approval is issued at the end of the procedure. The company can start importing or manufacturing before the issuing of the approval;
- Class III devices are registered at CAPA where a registration number and a marketing authorization are issued. The applicant cannot manufacture or import these products unless the registration number and marketing authorization are issued; and
- Single-use sterile medical devices are registered at CAPA (any class) where a registration number and a marketing authorization are issued.

As a general rule, all invasive items (sterile consumables or disposables) need to be registered at CAPA.

## **Registration of Class I, Class IIa and Class IIb devices at DPPC**

### **Step 1**

An importer or manufacturer should submit a request for approval in a file, on the company's letterhead with the company's stamp, to the DPPC (9 Emad EI Din Street, Cairo, Egypt, tel: +20-2-588-1317, tel/fax: +20-2-588-1202, email: samiasalah1@link.com) with the following documents:

- The license of registry in the list of importers of devices and medical equipment at CAPA;
- Invoices (or pro-forma invoices) for the equipment from the country of origin;
- The shipping bill;
- Detailed original (not photocopied) catalog(s) of the product(s) in question;
- For importing companies: proof (e.g. Contract) that the company is an approved agent or the sole distributor for the foreign parent company in Egypt;
- For importing companies: the S14 form (a form issued by the Ministry of Industry) that records the relationship between the Egyptian company and the foreign company (approved agent or sole distributor);
- If the importer is a company other than the sole distributor for Egypt (e.g. an additional distributor), an approval letter from the certified Egyptian sole distributor;
- If the importer is importing medical equipment or devices from a country other than the country of origin, an original letter from the parent company (certified by the Egyptian Embassy or Consulate) stating its approval for the importer to be a distributor for Egypt or the Middle East region;
- Details of a certified high-quality service center (for repairs), if applicable; and
- In the case of radiology or X-ray equipment, approval from the Office of Radiation Safety.

A new development is that for Class I non-sterile devices, the only requirement is a declaration of conformity (see below for definitions). For all other medical devices, one of the following documents is required:

- Original Free Sale Certificate stating that the product is freely sold in one of the reference countries (for medical devices, the reference countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, the UK and the USA);
- Original CE Certificate (a photocopy can be submitted in certain cases); or
- Original FDA Certificate.

An ISO certificate is not an acceptable alternative to these approved certificates.

## **Declaration of Conformity (Self certification)**

This is the certificate issued by the manufacturing company, which declares that the medical device in question conforms to the European directive. The conditions of acceptance for the declaration of conformity are as follows:

- It should cover the specific annexes required for the medical device (according to the device classification);
- The devices mentioned in the certificate should be identical to those in the invoice;
- The manufacturing company should be mentioned in the certificate;
- It must be the original certificate;
- It must be signed by the manufacturing company; and
- The authorized European representative must sign it in the event that the manufacturer resides outside the European Union.

## **Free Sale Certificate**

This is the certificate issued by the competent health authority, which states that the medical device mentioned is freely sold in a particular country. The conditions of acceptance for a free sale certificate are as follows:

- It should be valid;
- It should be certified by both the Chamber of Commerce and Egyptian Embassy or Consulate;
- The devices mentioned in the certificate should be identical to those in the invoice; and
- The manufacturing company should be mentioned in the certificate.

## **CE Certificate**

This is the certificate issued by a European notified body, which states that the medical device in question conforms to the European directive. The conditions for acceptance of the CE certificate are as follows:

- It should be valid;
- It should cover the specific annexes required for the medical device (according to the device classification);
- The devices mentioned in the certificate should be identical to those in the invoice; and
- The manufacturing company should be mentioned in the certificate.

A photocopy of the CE certificate can be submitted as long as DPPC personnel are able to contact the notified body and check the authenticity of the CE certificate. This does not always work, however, and sometimes the response of the notified body is very slow; in these cases an original CE certificate (certified by the Egyptian Embassy or Consulate) must be submitted.

## Special Applicants

Application files submitted by physicians to use equipment in a private clinic must include a copy of the clinic license. Application files submitted by hospitals must include a copy of the hospital license. Application files submitted by medical device manufacturers must include a copy of the factory license (issued by CAPA).

## Step 2

Following submission, the application is inspected by a group of DPPC-trained employees and is given an “in-document” serial number, only if all of the required documents are complete.

A new development is that a DPPC-trained pharmacist scrutinizes the application file. If necessary, the pharmacist checks the authenticity of the CE certificate by contacting the relevant notified body (see conditions of acceptance of CE certificate above).

Another new development is that a cover form is prepared by the assigned pharmacist containing a synopsis of all the necessary information about the medical device and the applicant. This form makes the inspection by the Specialized Committee for Study of Manufacturing and Import of Medical Devices and Equipment much easier. Applications are passed to the committee only when all the documents are complete and the assigned pharmacist has signed the cover form stating that the application file is satisfactory.

## Step 3

The medical device committee meets weekly to study the submitted complete applications. The committee has the right to request further documentation. For example, it can insist on an applicant submitting a free sale certificate or can request that both the CE and the FDA certificates are present. It can also ask for more detailed catalogue(s) or published scientific references demonstrating the efficacy and/or the safety of the device in question. If an application is accepted, an import approval will be granted by the committee stating the exact details of the equipment, and the accompanying invoices will be stamped. In addition, fees as detailed in Table I below should be paid to the DPPC.

Table I: Medical Device Registration Fees Payable to DPPC

<b>Invoice value (Egyptian pounds)</b>	<b>Fee (Egyptian Pounds)</b>
1,000	50
1,001–10,000	100
10,1001–30,000	200
30,001-50,000	300
>50,001	500

Exchange rate: 1 USD = LE 5.5

Once the importer receives an approval from the committee, he/she can import that medical equipment or device, provided that it is from exactly the same source. The importer will have

to submit a request to the DPPC for the release of a new batch, which should include a copy of the previous approval. A release approval will be issued to the importer within two working days; there is no need to go through the committee again.

### **Refusal**

If an application is refused, the reasons will be explained in detail to the importer. The importer then has the right to apply for an appeal to reconsider his/her application if he/she has some new documentation or evidence regarding the refusal argument(s) given by the committee. The importer will have to re-export the batch at his/her own expense.

### **Additional evaluation**

The committee has the right to consult any specialized medical institution or professors specialized in various medical fields, depending on the classification of the medical equipment or device in question. The final decision rests with the committee.

The committee also has the right to divert applications for modern, highly complicated medical equipment for evaluation to the Committee of Control on Newly Introduced Therapies at the MOH. This committee was established by Ministerial Decree No 255 in 1998 and has the role of inspecting such equipment that is introduced into Egypt for the first time.

To save importers' time and money, if an importer has doubts about a certain product, the DPPC personnel can agree to check the authenticity of a certain CE certificate before actually preparing the application file. Applicants are permitted to submit only a pro-forma invoice before actually importing the product.

### **Used or refurbished medical devices or equipment**

The import of any used or refurbished medical devices or equipment, even for private individual use, is strictly prohibited without prior approval from the MOH.

## **Registration of Class III devices at CAPA**

### **Step 1**

An importer or manufacturer should submit a registration file to the Head of Department of Registration at CAPA (22 Falaky Street, Cairo, Egypt, Tel: +20-2- 795-0106, Fax: +20-2-794- 5151). The registration file should contain the following documents:

#### **A- Imported products**

- A formal request to register the product on the company's letterhead stating the name of the product, name and contact information of the foreign company and the country of origin. The letter should be signed and stamped by the importer company;

- A formal letter on the company's letterhead with a pledge from the company that it will import this product only from the country of origin stated in the above-mentioned request. The letter should be signed and stamped by the importer company;
- The license of registry in the list of importers of devices and medical equipment at CAPA;
- A photocopy of the proof (e.g. contract) that the company is an approved agent or the sole distributor for the foreign parent company in Egypt (the original might be requested for comparison with the photocopy);
- The S14 form (see above);
- If the importer is a company other than the sole distributor for Egypt (e.g. an additional distributor), an approval letter from the certified Egyptian sole distributor;
- An original free sale certificate stating that the product is freely sold in the country of origin; certified by a health authority in the country of origin and the Egyptian Embassy or Consulate. If another authority in this country is responsible for registering medical devices, the chamber of commerce, for example, then an additional original official letter from this latter authority should be submitted stating this responsibility. This letter must be original and certified by the corresponding authority;
- An original, valid CE certificate certified by the Egyptian Embassy or Consulate stating the commercial name of the product in question, the name of the foreign company and the CE serial number. If the product's commercial name is not clear in the CE certificate, then either a declaration of conformity or a CE attachment should be submitted clarifying the commercial name;
- The original technical file, signed and stamped by the foreign company, containing:
  - A certificate detailing the full composition of the product (including any coloring matter or fragrances), mentioning the specifications and role of each of the raw materials;
  - The test method of the finished product;
  - The certificate of analysis of the finished product conforming with finished product specifications, issued by the quality control department at the manufacturing foreign company;
  - For sterile products, the certificate or the method of sterilization;
  - Sketch diagram and dimensions;
  - The certificate for the stability data (validity time);
  - The certificate explaining the material of packaging (external and internal if applicable) and the number of units in each package;
  - Internal and external label(s) of the product;
  - One sample of the product labeled with the name of the manufacturing company, the country of origin, number of CE certificate (identical with the submitted CE), manufacturing and expiration dates. If the manufacturing date is not mentioned on the submitted sample, then an original letter from the parent company should be submitted with a pledge from the company that it will export to Egypt the product labeled with both manufacturing and expiration dates, or that each batch exported to Egypt will be accompanied by a certificate of analysis stating the manufacturing and expiration dates of that batch; and

- In the case of presence or material of animal origin (bones, tissues, etc), a certified certificate of absence of BSE.

## **B- Local products and products manufactured under license**

- Formal request to register the product on the company's letterhead stating the name of the product, name and contact information of the foreign company and the country of origin. The letter should be signed and stamped by the importer company;
- Copy of the factory license (issued by CAPA); the original must be submitted for comparison with the photocopy;
- For products manufactured under license:
  - Copy of the valid contract with the Egyptian manufacturer. The contract must state clearly the product(s) to be manufactured. The certified original must be submitted for comparison with the photocopy;
  - Original Free Sale Certificate stating that the product is freely sold in the country of origin, certified by a Health Authority in the country of origin and the Egyptian Embassy or Consulate. If another authority in this country is responsible for registering medical devices, such as the Chamber of Commerce, then an additional original official letter from this latter authority is submitted stating this responsibility. This letter must be original and certified by the corresponding authority; and
  - CE certificate if available;
- The original technical file, signed and stamped by the manufacturing company, containing the same documents as mentioned above under imported products, except that the sample must have a label in Arabic and the words "made in Egypt" written in Arabic. Also the product must have both manufacturing and expiration dates; and
- In the case of presence of raw material of animal origin (bones, tissues, etc), a certified certificate of absence of BSE.

### **Step 2**

The file is examined by the Head Department of Registration and when all documents are satisfactory, the file is submitted to the High Technical Committee in two cases only:

- If the product contains raw material of animal origin; or
- If the product contains new ingredients or contains a compound with a pharmacological activity.

The High Technical Committee will give a decision on whether the product is considered a medical device or a pharmaceutical product.

### **Step 3**

All other files are submitted to the subsidiary committee at the DPPC. This committee meets every two weeks and studies the submitted file and gives its approval or refusal. If approved, a payment of LE 3,000 (\$526) is made to the DPPC by the company, and then a stamped approval is sent to CAPA with the file to finish the registration procedures.

#### **Step 4**

The file is submitted to the High Technical Committee, where the product is given a registration number and a marketing authorization valid for 10 years.

#### **Resources & Key Contacts**

Ministry of Health & Population

3 Magles El Shaab St., Cairo

Tel: +20 (2) 794-1507, 794-0526, 795-7046, Fax: +20 (2) 795-3966

Website: [www.mohip.gov.eg](http://www.mohip.gov.eg)

Central Administration for Pharmaceuticals Affairs (CAPA)

Ministry of Health & Population

22 El Falaky St., 2nd Floor, behind Magles El Shaab Street, Garden City, Cairo

Tel: +20 (2) 794-9227, 794-5151, 795-0106, Fax: +20 (2) 794-2627

Emails: [capa@mohip.gov.eg](mailto:capa@mohip.gov.eg); [moh@idsc.gov.eg](mailto:moh@idsc.gov.eg); [webmaster@mohip.gov.eg](mailto:webmaster@mohip.gov.eg)

Website: [www.mohip.gov.eg](http://www.mohip.gov.eg)

Drug Planning & Policy Center (DPPC)

Ministry of Health & Population

9 Emad Eldin St., 2nd Floor, Cairo

Tel: +20 (2) 588-1317, 588-1773, Fax: +20 (2) 588-1202

Email: [samiasalah1@link.com](mailto:samiasalah1@link.com)

Registration Department

Ministry of Health & Population

22 El Falaky St., Cairo

Tel: +20 (2) 795-0106, Fax: +20 (2) 974-2627

National Organization for Drug Control and Research (NODCAR)

Ministry of Health & Population

Mohandessin, Cairo

Tel: +20 (2) 748-4988, Fax: +20 (2) 337-9445

#### **For More Information**

The U.S. Commercial Service in Cairo, Egypt can be contacted via e-mail at:

[Jihan.Labib@mail.doc.gov](mailto:Jihan.Labib@mail.doc.gov); Phone: +20-2-2797-2223; Fax: +20-2-2795-8368, or visit

website: <http://www.buyusa.gov/egypt/en>