

Medical Device Regulatory Requirements for Egypt

Introduction to the Egypt Regulatory System

The Ministry of Health and Population (MOHP), is the key government agency charged with meeting Egypt's healthcare needs and regulations. MOHP is the organization that manages and coordinates standardization activities in Egypt. There is little local medical equipment production so the market relies mainly on imports and is extremely receptive to American medical products because of the advanced technology and associated training, well-developed marketing systems, as well as financing available through U.S.AID's Commodity Import Program. FDA approval is key to having medical products registered, although the Ministry of Health may still do additional testing on any medical device.

Standards issued by the Egyptian Organization for Standardization and Quality Control (EOS) are applied to some specific medical measuring devices and instruments. With respect to other medical products where no mandatory standards exist, the following international standards are adopted: International Standards ISO/IEC; European Standards (EN) – (in the absence of EN standards, British (BS), German (DIN), and French (NF) standards may be applied); American Standards (ANSI); and Japanese Standards (JIS). In the absence of an Egyptian or international standard, authorities often will refer to the Analysis Certificate accompanying the product.

The importation of used and refurbished medical equipment and supplies to Egypt is banned. The ban does not differentiate between the most complex computer – based imaging equipment and the most basic of supplies. At present, even new medical equipment must be tested in the country of origin and proven safe before it will be approved for importation into Egypt. The importer must submit a form requesting the Ministry of Health's approval to import medical equipment. The importer will attach to the request a certificate issued by official health authorities in the country of origin, indicating that the medical equipment, subject to importation, is safely used there.

The importer will also present an original certificate from the manufacturer indicating the production year of the equipment and that it is new. In addition, the importer will present a certificate of approval from the Food and Drug Administration (FDA) or a certificate of approval from the European Bureau of Standards. The importer must prove that it has a service center that can provide after sales support for the imported medical equipment, to include spare parts and technical maintenance. The MOH's technical committee will examine and review the technical specifications of the equipment before granting an approval to admit it into Egypt. These regulations also apply to medical equipment that is being donated, not sold for profit.

Documents Required for Approving Medical Devices/Equipment:

The Drug Policy & Planning Center of the Egyptian Ministry of Health requires the following documents in order to register and approve medical devices and equipment:

1. Copy of Pro-forma Invoice
2. Copy of FDA approval (Certificate to Foreign Government) signed and sealed by the Egyptian Embassy/Consulate in the US.
3. Copy of the legalized Agency Agreement

4. Catalog or literature (hard copy or CD)

1. The FDA approval is the key to have medical devices/equipment approved by the MOH in Egypt.

2. Local importers could obtain a “Pre-Approval” of products they intend to import before actual shipment arrives at customs and could wait for a long time until approval procedures are complete. This way will save a lot of time, effort and cost. Importer needs to present only a Pro-forma Invoice, and the Certificate to Foreign Government to the DPPC of the MOH. The pre-approval takes about one week to be granted.

Documents Required to Register Medical Disposables

1. Registration request stating the product, the manufacturing company and the country of origin, signed and stamped by the requesting company.

2. An affirmation that the imports will only be from the country of origin, signed and stamped by the company.

3. A copy of importers record register in the Ministry of Health and Population naming the manufacturing company and the original for inspection.

4. A copy of the registered effective contract and the original for inspection. In case of an intermediate company or branch, the relationship with the mother company should be clearly indicated in full details and registered.

5. The Original Free Sale Certificate signed at a Health Authority and registered in the Egyptian Embassy in the country of origin. It should indicate the commercial name of the product, the name of the manufacturer, his address and state that the product is being freely sold in the country of origin. In case there is no health Authority and there is another entity that is responsible for medical disposables, such as the Chamber of Commerce and Industry, this entity should provide a signed letter indicating its responsibility for registering such products in the country of origin.

6. CE certificate or FDA approval signed, effective and indicating the name of the product, the name of the manufacturer and the CE number. In case the commercial names are not clearly stated within the CE/FDA certificate, a declaration of conformity or a CE/FDA attachment should be given clarifying the names of all products and their commercial names as well.

7. The Technical File consisting of the following: (all originals signed and stamped by the manufacturing company)

A certificate of the raw materials indicating the specifications of the materials used and the reason for their presence in the product. For colors and scents, the raw materials used to create them should be indicated. A certificate of the analysis procedures and a certificate of the analysis of the final product and its conformity to the manufacturing specifications. This certificate should be issued by the quality assurance center in the factory. If the product is sterile, a certificate of sterilization procedures is needed. Certificate of the sketch diagram and dimensions with the product name. Certificate of the validity period. Certificate indicating the packaging procedures, the materials used in making the packages, number of units in each package and in the outer package and the labels on the inner and the outer packages.

8. A sample from each item to with the following information indicated upon:

The manufacturing company name. The CE/FDA number indicated in the CE/FDA certificate included in the file Manufacturing date and the expiry date In case the manufacturing date is not mentioned on the package a letter signed and stamped by the company indicating it accepts to write to the manufacturing date on the products that would be released in the Egyptian market or a letter signed and stamped by the company indicating it accepts to send a certificate on the manufacturing date with each shipment exported to Egypt.

1. In case of materials extracted from animal origin (bones, tissues, brain etc.) a certificate issued by the Ministry of Health in the country of origin indicating that it is clear from the causes of mad cow disease. This matter should be presented first to the technical committee of drugs inspection to give a decision whether this product is pharmaceutical disposable or a pharmaceutical drug.

2. In case the product contains a medical material or an unknown material, the matter should be presented to the technical committee of drugs inspection to give a decision whether this product is pharmaceutical disposable or pharmaceutical drug.

Market Access-Customs/Other Charges

Custom tariffs on medical equipment and devices are 2% plus 10% sales tax. In addition, there are other miscellaneous fees such as customs clearance, demurrage and transportation charges, bank commission, etc. Total costs could amount to 17%.

Egyptian law also requires that for public tenders, foreign companies must retain Egyptian commercial agents. Foreign firms are not required to have an agent when dealing with the private sector or for sales financed by USAID or USDA. However, most foreign companies have found it beneficial to engage a local agent to handle the problems associated with communications, bureaucratic procedures, local business practices, and marketing. Based on geographical location or product basis, a firm can appoint multiple agents in Egypt to further enhance its success. Although agents commissions vary with services provided and the amount of individual contracts, agents generally charge a commission ranging from 2-4% for opening credits and 1-2% for clearing goods through customs.

Parastatal companies purchase commodities through call for international tenders. These are announced in the daily Egyptian press. US firms must use an Egyptian agent to purchase tender documents from the issuing sector entity. In many cases, US firm may not be able to provide variety of products required in large tenders. With the formation of a consortium, however, it can offer a bid. The Italians, German and the Japanese have successfully used this technique in Egypt. Egyptian buyers prefer a single bid for an entire tender rather than having to piece together bids for each component.

Public sector companies may request credit in their procurement tenders. While suppliers offering credit will certainly have a better chance of winning bids, sales without credit are sometimes made since other factors such as price, quality, and a delivery schedule may be of greater importance.

Public sector companies generally also require a performance bond equal to 10% of the contract releasable upon completion of the contract. To avoid delays in obtaining release

of the performance bond, the contract must be formally amended if the buyer requests any change in delivery terms or specifications.

U.S. firms should be aware that while the purchasing company may simply accept the lowest bid meeting specifications, it may also attempt to bargain with one or more of the lowest bidders to negotiate better terms. Therefore, US firms should be prepared to empower their agents to do so. On major contracts, it is advisable to have an American representative conduct such bargaining.

There are no language requirements in Egypt. Although Arabic is the official language, English is acceptable. The country uses the metric system of measurement, but bids will not be rejected if another system is offered unless the tender specifically requires metric measurements.

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埃及医疗器械法规要求

埃及医疗法规体系简介

MOHP 人口卫生部，作为政府重要机构，负责埃及医疗健康事业和法规的制定。并且负责管理和协调标准化工作。当地的医疗器械生产企业很少，所以市场需求主要依靠进口，并且很乐于进口美洲等国的产品，基于他们先进的技术和相关的技术培训，成熟的营销体系。并适时由美国国际商品援助计划进行资助。虽然卫生部会做进一步的医疗器械测试，但 **FDA** 的产品注册登记才是关键。

标准由埃及标准化与质量控制组织颁布，适用于某些特殊的医疗诊断仪器和设备。对于没有现存强制标准的其他医疗产品，等同采用国际标准：国际标准 **ISO**、欧洲标准 **EN**（在缺少欧洲标准的情况下，英标、德标、法标也可以采用）、美国标准、日本标准。在缺少埃及标准或国际标准的情况下，主管当局需参考产品随机检测报告。

埃及是禁进口翻新使用的医疗设备，该禁止不存在区分对待--基于影像设备或其他基础设备计算机的复杂程度。目前，任何新医疗设备在批准进口至埃及前，需要检查其原产地销售证明和安全证明，进口商需要递交进口申请至卫生部，用于医疗器械设备的批准，进口商附上原产国官方卫生机构出具的证书，注明此医疗设备的进口概述，及安全使用声明。

进口商同时需提交制造商的原产地证明，标明新设备的生产年份。另外，进口商需要提交由 **FDA** 批准的证明或欧洲标准局的批准证明书。进口商必须证明有一个服务中心为进口医疗设备提供售后服务支持，包括零配件和技术维护。在正式出具批准允许产品进口至埃及之前，**MOH** 卫生部技术委员会将会检查和评审设备的技术说明书，此项法规同样适用于医疗设备的无盈利性的活动，比如捐赠。

医疗器械/设备获批的文件要求：

埃及卫生部药物行政和规划中心要求递交一下文件用于医疗器械与设备的批准登记：

1.形式发票复印件

2.经埃及大使馆/领事馆签字和盖章的 **FDA** 认证（致外国政府的认证书）复印件。

3.合法的代理协议复印件

4.产品目录文献（硬盘或 **CD** 拷贝件）

1.FDA 的批准是医疗器械被 **MOH** 批准前的最重要的步骤

2.在产品实际装运到达客户之前，当地的进口商可以获得一份预进口产品的‘形式批准’，因为在全部的批准手续完成之前，他们可能需要等待很长一段时间。这样可以节省一些时间、工作和成本。供应商目前只需要递交形式发票，和致外国政府的出口销售证明书，递交到埃及卫生部药物行政和规划中心。受理形式批准大约需要一周的时间。

医疗耗材注册的文件要求：

1.注册产品、制造公司、原产国的要求说明书，需求公司的签名，盖章。

2.原产国进口的声明，并由公司签名，盖章。

3.用于人口卫生部的供应商登记注册复印件，制造商和原检验记录。

4.经登记注册的有效合同和原检验记录，如果是分公司或子公司的情况，应明确指出其与母公司的关系与注册登记状态。

5.原自由销售证明书由卫生部签发，并经埃及驻原产国大使馆登记注册。需要标明产品的商品名、制造商名称、地址和产品在原产国的销售状况等信息。如果不是由卫生部，或者说由其他机构全权负责医疗耗材，比如商会或行业，其需要提供一封签名信用于声明此机构在原产国负责此产品的登记注册。

6. CE 认证或经 FDA 签署或批准，有效的标明产品名称，制造商名称和 CE 证书号。若 CE/FDA 证书没有清楚地标明商品名称，最好能够递交一份用于标明产品名称和商品名称的符合性声明或 CE/FDA 的声明文件。

7.技术文件由以下组成：（所有正本由制造商签名盖章）

原材料证明书用于标明材料的使用状况和在产品中使用的原因。对于原材料产生出的颜色和气味，需要进行标明，其质量保证部门签发一份过程分析证明/最终分析证明和其符合制造规范。如果产品是无菌的，需要一份灭菌过程证明。产品素描图及尺寸的证书、产品有效期证书、产品包装证书、包装用材料、在外包装上注明每包装的单位个数，内外包装都需要标签。

8.每个项目的样本需要在以下标明：

产品制造商名称、CE/FDA 证书号且显示证书的颁发日期和有效期。如果产品在包装上没有标明生产日期，就需要递交由制造商签名和盖章的信函，其承诺生产日期注明在产品上，可以投放至埃及市场。或者承诺递交一份每次装运的制造日期文件至埃及。

1.如果是从动物中提取的原料（骨骼、组织或大脑等），需要有一份由原产国国家卫生部签发的证书，用以标明其不会引发疯牛病。此类问题需第一时间递交至药物监督技术委员会，使其给出一个决定其是一次性药剂还是药品药剂。

2.如果此产品含有医用材料或未知材料，此类问题需第一时间递交至药物监督技术委员会，使其给出一个决定其是一次性药剂还是药品药剂

海关-市场准入/其他收费

针对医疗器械的自由贸易关税在 2%，另加 10% 销售税。另外还有其他的杂项收费比如报关费、海关滞留费，运费和银行手续费等，总的费用可能达到 17%。

埃及法律还规定公开招标，外国公司必须拥有埃及商业代理，外国公司不需要其代理处理美国国际开发署和美国农业部的私营部门或销售融资。甚至，大多数外国公司发现聘请当地的代理处理交流，与官方的联系，当地的商业惯例和市场非常有帮助。基于地理位置或产品特性，公司可以聘请多个埃及的代理来达成目的。所提供服务的代理佣金和个人合同金额，代理一般信用并公开收取 2-4%不等的佣金，和商品通关货物价值的 1-2%的佣金。

半官方的公司采购商品通过国际招标进行，由埃及新闻界进行宣布。美国公司需要通过代理购买实体发行部门发行的招标文件。很多情况下，美国公司不能提供大型招标所需的产品种类。随着财团的形成，它可以出价，在埃及，意大利、德国、日本已经成功运用此项方式达成目的。埃及采购商更倾向于整体价值投标而不是各个组件组合报价。

政府公共部门需要采购投标商的信用担保，供应商能提供信用担保是其更好地中标的保证，销售如果没有信用担保，比其他因素例如价格、质量、交货期更为重要。

政府公共部门通常需要 **10%** 的合同完成后的保证金，用于避免产品交货延误。当采购者需要变更交货条款或任何说明时，采购合同必须正式重新修订。

美国公司应该知道当采购方唯一接受符合要求的最低中标价时，采购方仍然会与最低中标者进行讨价还价，已达成更好地条件。美国公司可以授权代理人去做这些。在重大和同时，最好由美国代表来进行合同谈判。

在埃及没有语种限制，虽然阿拉伯语是官方语言，但英语也是可行的，国家实行公制计量体制，如果提供另一种体制，其出价也将被视为接受，除非招标具体要求公制。

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