

Regulatory Reforms for product Registration and factory licensing

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Introduction

- **The medical devices sector is very sensitive and critical because it deals with health directly and it faces many changes and difficulties.**
- **Local production and imported products have to meet minimum safety requirements and high quality performance which apply international and Egyptian standards.**



IDA's coordination role

One of IDA goals is to build relationships with partner organizations:

- Ministry of Health.
- Federation of Egypt Industries represented in Medical industries sectors.
- Industrial Modernization Center (IMC).
- Egyptian Organization For Standards and Quality.
- which deal with the medical devices industry to organize and set the main criteria for this critical sector



Medical devices are divided into:

- **Medical Equipment and Furniture.**
- **Medical Supplies.**



International Classification of medical devices according to the EU directives:

Three main Classes: first, second and third class , with a simple set of classification rules based on:-

1. Technical features of the medical devices.
2. Duration of contact with the patient, degree of invasiveness and the part of the body affected by the use of the device.



International Classification of medical devices according to the EU directives - Continued :

1. Non invasive devices :

Do not touch patient, contact or only intact skin ,modify biological or chemical, composition of blood, body liquids.



International Classification of medical devices according to the EU directives - Continued:

2. Invasive devices:

In whole or in part, penetrates inside the body, through a body orifice or through the surface of the body.

3. Active devices:

The operation of which depends on a source of electrical energy or any source of power.



Rules and framework

There is an agreement signed between IDA and Ministry of Health to set administrative requirements and to organize the procedures for registering and licensing the medical equipment, furniture and supplies (sterile and non-sterile)



Rules and framework - Continued:

1) Medical equipment and furniture:

- **Relate to general control first class and some of which depends on source of power relate to the second or third class.**
- **The award of an industrial registration certificate depends on:**
 - A. The presentation of a technical assistance contract certified and authenticated from an international company.**
 - B. Alternatively submission of detailed engineering drawings similarly approved.**



Rules and framework - Continued:

2) Medical supplies:

- A. **Sterile Supplies**: The award of industrial registration depends on the product being registered at the Ministry of Health.
- B. **Non-sterile supplies**: The award of industrial registration requires, either by:
- Presentation of a conformity certificate issued according to Egyptian or International specifications by one of the specialized scientific associations in Egypt
 - Obtained CE Mark certificate.



Rules and framework - Continued:

The Non-Sterile products are divided according to the level of risk to human health :

1. Products that do not represent any risk or harm to human health such as surgical clothing:

IDA will only request an accredited standard specification.

2. Products that represent a high level of risk such as Orthopedics will require a technical assistance contract, approved and documented by one of the specialized associations



Services provided by IDA within the sector of Medical Devices projects



- 1. Allocation of industrial lands in new industrial cities and initial approval of establishing projects.**
- 2. Final approval of establishing projects in the new industrial cities & industrial zones of governorates.**
- 3. Issuing of modifying or extensions.**
- 4. Approval of registration in the industrial registry.**



The technical data required to obtain the final approval:

- 1. Items to be produced and their annual production capacity for one shift.**
- 2. List of Production Materials and Components Necessary for the Project Annually.**
- 3. List of Machinery & Equipment Used in the Project.**
- 4. Energy and Utility needs.**



The data required to obtain the final approval :

A) Sterile products:

1- Obtaining the ministry of health license for the project.

2-Registration of the products at the ministry of health

3- National or international conformity certificate.



The data required to obtain the final approval - Continued :

B) Non-Sterile products:

Applying the Ministry of health requirements if found .

The product should be conformed to the Egyptian or
international specification

Conformity of the raw material to the specification .



OBTAINING THE ESTABLISHMENT REGISTRATION CERTIFICATE (VALID FOR 5 YEARS)



IDA does not provide the approvals for the following products :



- 1. Packaging or sterilizing of medical devices without any industrial process.**
- 2. Assembling of sterile medical devices dealing with blood directly such as:-**
 - hmodiayalyses filter.**
 - blood lines.**
 - blood bags.**
 - Transfusion sets and syringes.**



Summary of steps to establish a medical devices project:

- 1. Allocation of lands in industrial zone**
- 2. Initial approval of establishing project.**
- 3. Final approval of establishing medical project located in a certain industrial city from IDA.**
- 4. Getting license from the ministry of health**
- 5. Register the products in (MOH).**
- 6. Getting IDA INDUSTRIAL Reregistration.**



IDA

“Make doing business in the industrial sector easy”



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