Serial: 00001 / yyyy

Documents required for the release of imported Medical Devices

1-Formal Request (Invoice number, Invoice date, Invoice valve, Product name, Company Name, Country of Origin) Signed& stamped from the importing company To obtain approval for importation of medical device.
2- 3copies of Performa Invoice described the country of origin.
3-Importer Record License of Egyptian company Added to the foreign company + photocopy of agreement+C14 in case of agents.
4-Commercial register and the tax card .
5-Distribution /Agency Agreement) between importing Egyptian and exporting foreign company Valid date and a fixed-term ,in case the foreign company is not added in Importing license.(Original & Legalized by chamber of commerce and Egyptian embassy in foreign company.+ photo copy.)+ Write a pledge to add the company supplied in the license registration under the contract prior to the import again
6-Relation between foreign Exporter &foreign Manufacturer (Original& Legalized) (in case subcontractor or broker) +photo copy.
7-Catalog shows the logo for the factory and use the product and Models and matching it.
8- Required to provide certificates of quality coming from the same country of origin of the accessory and matching them, namely: **1-Declaration of conformity certificate shows the following:** • **That entails a quality or medical device manufacturer is responsible for foreign +Declare Purpose and Use.** • **Classification of the medical device (class l, class lla, class llb, class lll).** • **MALE quality CE certificate number on the product and follows the Medical Device Directive.** **2- Certificate of CE (Medical directive 93/42/EC) and the Annex containing the appropriate classification entails a (out of documented from the Embassy and Chamber of Commerce) would remain in history + image (if only to bring the image of the lab is waiting for a response on the CE)** ***In case of product contains material of animal origin is required to contain CE on BSE directive 2003/32/EEC.** ***In case of import of medical equipment from countries other than the reference is to bring different ERP sealed Declaration of the European Laboratory documented out of the embassy and the Chamber of Commerce (in the case to bring the image to be waiting for a response lab).** **3-Certificate of Free Sale from the country of origin valid date (out of documented from the Embassy and Chamber of Commerce), including the brand name of the product (if any) + Image**

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***In the case of sterile supplies, which are recorded are brought Free Sale from the country of reference if the reference is the country of origin.** ***In case of non-sterile medical supplies are classified Class IIB & III Free Sale is brought from the country of reference if the reference is the country of origin.** **4-or a certificate of FDA (continued) instead of the CE & Free Sale, including the brand name of the product (if any) would remain in history + image ((in the case brought in a picture with the Serial Number is only awaiting a response from the FDA**
9-Marketing Approval of the product sterile issued by the Central Administration of Pharmaceutical Affairs.
10-Approval of the Executive Bureau of the rays in the case of X-ray equipment.
11-Approval of the National Institute for the laser science in the case of lasers.
12-In case of import of spare parts for the medical device is presented certificates to the above-mentioned device and a piece suggesting that the parts belong to the device provided with quality certificates.
13-Result of the analysis sample from the Faculty of Engineering Supplies bone from countries other than the reference.
14-Prior approval (if any).
15-Pledged that it will be contained in the data fully describes the manufacturer and supplier of foreign company (if applicable) and country of origin written on it (Made in…….)

<u>In case of importing a hospital or doctor is required to provide:</u>

1. **Formal Request for the release of medical devices.**
2. **3copies of Performa Invoice described the country of origin.**
3. **licensed medical facility (hospital or clinic) of the treatment for free to the Director of Health Affairs eagle stamped with a license to practice the profession.**
4. **Certificate of quality of items of invoice.**
5. **Catalog.**
6. **the approval of the agent (if any).**

<u>In case of importing a patient for personal use:</u>

1. **Formal Request for the release of medical devices.**
2. **3copies of Performa Invoice described the country of origin.**
3. **Report of a medical facility.**
4. **Pledged that entails a responsibility on the patient without any responsibility on the Ministry of Health.**
5. **Catalog.**
6. **Certificate of quality if he could get it.**

<u>In the case of aid or donations:</u>

1. **Formal Request for the release of medical devices.**

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2- 3copies of Performa Invoice described the country of origin.
3- A letter from the Grantee to accept the gift and responsibility regarding private without any responsibility on the Ministry of Health.
4- Certificate of quality.
5- Catalog.

In the case of repair:

The Company applied for central administration of the Pharmaceutical Affairs for approval to export the device to the repair facility by the following:

*Provide the user to enter the new device before sending it off for repair and to provide

-Prior import approval issued by the central administration.

-Or the sending device for reform would be through the agent or distributor under contracts approved documented to do so.

*Invoice issued by the importing company for the device to take the approval of the central administration of the services to be exported To repair and run-off by the Serial Number for each device.

*A copy of the Register of Importers of medical equipment and supplies added to the device manufacturer to be repaired.

When run-off:

1-is to provide a invoice which was approved by the central administration, which the serial number of the source device for repair and stamped by Customs.

2-A copy of Form 126 as issued by the customs with the same serial number is identical to a bill issued by the central administration, signed and stamped by the Customs (out for).

3-the invoice received from the maintenance center approved by the manufacturer is identical from the customs.

4-Inbound customs certificate.

N.B:

*The status of the file should be followed up within 72 hours only from date of application to fulfill its requirements.

*Copies of the file of the new devices that are imported to Egypt for the first time are required to be submitted to a specialized committee to have their opinions about the quality and efficacy of these new devices.

*In all cases of import of medical equipment received each time ,it must submit a request to release imported initial invoice before The actual shipment of the machines so as to avoid delay in the release of the cargo after arriving at the port of destination.

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