



Egyptian Drug Authority  
Authority Presidency

## **Chairman Decree No. (190) of 2022 Regarding the Issuance of Import permit Approvals for Medical equipment, their Accessories and their Spare Parts**

### **Chairman of the Egyptian Drug Authority:**

#### **Having perused:**

- Law on Pharmacy Profession Practice No. (127) of 1955, and its amendments;
- Law on Establishing the Egyptian Drug Authority Promulgated by Law No. (151) of 2019, and its Executive Regulation;
- Minutes of the Authority's Board of Directors' meeting held in its session on 20/7/2020;
- Decree of the Chairman of the Authority No. (2) of 2021 Regarding the Rules Regulating the Registration and Circulation of In vitro Diagnostic Medical Devices;
- Decree of the Chairman of the Authority No. (205) of 2021 Regarding Setting the Services' fees for In Vitro Diagnostic medical devices by the Central Administration of Medical Devices;
- Decree of the Chairman of the Authority No. (425) of 2021 Regarding Setting the Services' fees for Importing Production Inputs and Components for Local Factories by the Central Administration of Medical devices;
- Decree of the Chairman of the Authority No. (430) of 2021 Regarding the Regulatory Procedures for Registering Imported and Local Medical Devices that Have International Quality Certificates;
- Decree of the Chairman of the Authority No. (499) of 2021 Regarding Using the International Barcodes of goods for All Medical Devices Circulated in the Local Market;
- Decree of the Chairman of the Authority No. (585) of 2021 Regarding the Procedures and Rules Required for Obtaining Import permit Approvals of Laboratory and Diagnostic equipment and their Accessories;
- Decree of the Chairman of the Authority No. (642) of 2021 on the Data of the Labels of medical devices, laboratory and In Vitro Medical Devices, and Production Inputs and Components;
- Decree of the Chairman of the Authority No. (88) of 2022 Regarding the Issuance of Import permit Approvals for Medical Devices of all their types;
- Based on what's submitted by the head of the central administration of medical devices;
- and in the interest of work;





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**decided**

**(Article One)**

This decree shall apply to the issuance of import permit approvals required for medical equipment, their accessories and their spare parts.

**(Article Two)**

It shall not be permissible to import medical equipment, their accessories and their spare parts except after obtaining an import permit approval from the competent department at the Central Administration of Medical Devices in accordance with the regulations applicable to the Egyptian Drug Authority.

**(Article Three)**

The Head of the Central Administration of Medical Devices shall, within five days from the date of the approval of this decree, issue the regulatory guideline for issuing import permit approvals for medical equipment, their accessories and their spare parts.

**(Article Four)**

The entities of importing, manufacturing or distributing medical equipment, their accessories, or their spare parts shall be committed to all the technical requirements and procedures mentioned in the aforementioned regulatory guideline.

**(Article Five)**

The fees attached hereto shall be collected in return for the services provided by the Central Administration of Medical Devices for issuing annual import permit approvals of medical equipment, their accessories and their spare parts, laboratory, diagnostic equipment and their spare parts.

**(Article Six)**

The service fees shall be deposited in the accounting unit of the Egyptian Drug Authority.

**(Article Seven)**

This decree shall come into effect from the day following its issuance and any other provisions that may contradict this decree shall be repealed.



**Chairman of  
Egyptian Drug Authority**

**Prof. Tamer Mohamed  
Essam**

**Written on: / /**