



Egyptian Drug Authority
Authority Presidency

Chairman Decree No. (429) of 2021
Regarding the Regulatory Procedures for Registering Imported and Local
Medical Devices Holding International Quality Certificates

Chairman of Egyptian Drug Authority:

Having perused:

- Law on Pharmacy Profession Practice No. (127) of 1955, and its amendments;
- Law on Establishing the Egyptian Drug Authority No. (151) of 2019, and its executive regulations;
- Based on what's submitted by the head of the central administration of medical devices;
- And in the interest of work;

Has decided

(Article One)

The regulatory rules attached to this decree shall apply to the regulatory procedures for registering imported and local medical devices holding international quality certificates and classified according to the classification listed in the attached guideline.

(Article Two)

This decree shall apply to applications submitted for the registration of imported and local medical devices which hold international quality certificates and which are subject to this decree and it shall also apply to all applications submitted for the re-registration of the aforementioned medical devices as from the date of issuance of this decree.

(Article Three)

Imported and local medical devices which hold international quality certificates and which are subject to this decree shall not be permitted to be circulated except after their registration in the Egyptian Drug Authority in accordance with the grace periods mentioned in the attached guideline.

(Article Four)

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come into effect from the day following its issuance and any other provisions that may contradict this decree shall be repealed.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

