



Egyptian Drug Authority
Authority Presidency

Chairman Decree No. (469) of 2021 Regarding the Guideline of Introducing a Change on a Registered Medical Device

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)

This decree shall apply to the procedures and rules regulating implementing a modification in the data of the registration license of a medical device.

(Article Two)

The holder of the registration license (Applicant) of the medical device shall be obligated to inform the variation administration in the Central Administration of Medical Devices about any modifications that occur to the medical device. The modifications referred to herein are divided into: modifications that can be notified of after their implementation, modifications that shall be notified of before their implementation and modifications that shall be notified of and reviewed before their implementation.

(Article Three)

The Head of the Central Administration of Medical Devices shall, within fifteen days from the date of approving this decree, issue a regulatory guideline of the procedures and rules regulating the implementation of a modification in the data of the registration license of a medical device.

(Article Four)

This decree shall come into effect from the date of its issuance and any other provisions that may contradict this decree shall be repealed.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: / /