



Egyptian Drug Authority
Authority Presidency

Chairman Decree No. (424) of 2022
Regarding the Regulatory Procedures for Registering Local Medical
devices not 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 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 20/07/2020
- 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 be applied to the Regulatory Procedures for Registering Local Medical devices not holding International Quality Certificates.

(Article Two)

The local medical devices which don't have international quality certificates and classified according to the classification included in the accompanying guideline shall be prohibited to be circulated, except after being registered in Egyptian Drug Authority.

(Article Three)

The Head of the Central Administration of Medical Devices shall issue the regulatory guideline of the procedures and rules for registering local medical devices which do not have international quality certificates, within five working days from the date of approving this decree.

(Article Four)

Factories manufacturing non-sterile local medical devices which do not have international quality certificates shall comply with all the technical requirements contained in the aforementioned regulatory guideline. These factories may regularize their conditions within one year from the issuance date of the aforementioned regulatory guideline and notify the competent department of Egyptian Drug Authority.





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(Article Five)

The fees stipulated in the attachments of this decree shall be collected in return for the services provided by the Central Administration of Medical Devices regarding the registration of local medical devices which don't have international quality certificates.

(Article Six)

The services ' fees determined shall be deposited in the account of Egyptian Drug Authority's unit of account.

(Article Seven)

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 Any other provisions that may contradict this decree shall be repealed.

**Chairman of
Egyptian Drug Authority**

Prof. Tamer Mohamed Essam

