In the Name of God, Most Gracious, Most Merciful

Kingdom of Saudi Arabia

Saudi Health Council

General Secretariat

Resolution No. (84/4)

Date: 16/4/1440

Subject: A guide for good practice of the management of medical devices and products and the regulation of the control of medical devices and products.

The Saudi Health Council:

After reviewing the letter of His Excellency the CEO of the Food and Drug Authority No. S / 73574 dated 12/3/1439 AH regarding the Authority's preparation of a good practice guide for the management of medical devices and products within health care facilities and His Excellency's letter No. 4/4941 dated 1/21/1440 AH The implication is that the Food and Drug Authority system or an agency that regulates and monitors medical devices and products, ensures the accuracy of medical and personal device standards and their safety for human health, and monitors health facilities 'compliance with international safety standards**.**

And after reviewing the recommendations of the Preparatory Committee at its forty-ninth meeting on 3/4/1440 AH

And after reviewing the offer submitted by the Vice President of the Food and Drug General Authority for medical devices and equipment.

After that, the Council discussed the issue at the eighty-fourth meeting, held on 4/16/1440 AH

the following was decided:

1. Obliging the health sectors to direct all their health facilities to manage and calibrate their measurements, quality and specifications for operating and maintaining medical devices through medical engineering departments or a third party licensed by the Food and Drug General Authority.

2. Require from health sectors to report incidents to medical devices and products to the Food and Drug General Authority.
3. Requiring from health sectors to apply the terms and requirements of the Food and Drug Authority to use a safe medical device for diagnosis and treatment.
4. The Saudi Center for Accreditation of Health Facilities (CBAHI) considers the use of a safe medical device for diagnosis and treatment as part of the requirements and requirements for accreditation for health facilities.
5. Requiring health sectors to train health practitioners working for them to operate the use of medical devices, as well as medical device engineers, by an entity or person approved by the company that manufactured the device or product.
6. Requiring health sectors to use the guidelines for good practice for managing medical devices and products within health facilities, which is published on the Food and Drug Authority website.

Minister of Health

President of the Saudi Health Council

Tawfiq bin Fawzan Al-Rabiah

On his behalf: **Fahd bin Abdul Rahman Al-Jalajil**

Deputy Minister of Health

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رئيس المجلس الصحي السعودي
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