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**Supreme Council of Health**

**Decision No. (48) of 2020 regarding Medical Devices and Products’ Quality Control**

President of the Supreme Health Council:

Having reviewed the Legislative Decree No.(2) of 1987 regarding Practice of Non-Doctors and Pharmacists of Allied Medical Professions;

Legislative Decree No. (7) of 1989 regarding the Practice of Human Medicine and Dentistry;

Law No. (38) of 2009 Establishing the National Health Regulatory Authority as amended by the Legislative Decree No. (32) of 2015;

Legislative Decree No. (21) of 2015 regarding the Private Health Institutions, as amended by Law No (1) of 2019;

The Health Insurance Law promulgated by Law No. (23) of 2018,

The Public Health Law promulgated by Law No. (34) of 2018,

Decree No. (5) of 2013 establishing the Supreme Council of Health, as amended;

Decision No. (2) of 1977 regarding the Specifications, Requirements and Health Equipment that must be Available in Private Doctors’ clinics;

Decision No. (21) of 1987 regarding Licensing Procedures for the Establishment and Management of Private Hospitals;

Decision No. (22) of 1987 regarding Health, Technical, and Safety requirements to be fulfilled in Private Hospital Establishments and Equipment;

Decision No. (3) of 1995 regarding the Conditions, Specifications, and Medical Equipment that shall be Available to Authorise Doctors to open Private Clinics for 24 hours and on Official Holidays, as amended by Decision No. (1) of 2003;

Decision No. (1) of 2001 regarding the Management of Hazardous Waste for Health Care;

Decision No. (3) of 2014 regarding the Regulation of Medical Centres;

Decision No. (4) of 2014 regarding the Regulation of Radiation Applications in Health Institution;

Decision No. (20) of 2016 regarding determining fee categories for Private Health Institution;

Decision No. (24) of 2016, promulgating a list of Allied Health Professions;

And Decree No. (2) of 2019 regarding the Classification of Private Health Institutions and the Technical and Safety Requirements to be met in their Institution and Amenities,

And after the approval of the Supreme Council of Health,

Based on the presentation of the Chief Executive Officer of the Authority of the National Health Regulatory.

**Hereby Decides:**

**Definitions**

**Article (1)**

In applying the provisions of this Decision, the following words and expressions shall have the meanings assigned to them:

**Kingdom:** The Kingdom of Bahrain.

**Authority:**The National Health Regulatory Authority.

**Person:** The natural or legal person.

**Medical devices and products:**

a) A machine, tool, medical application device, implant, laboratory reagents and standards, software, operating hardware, or any similar or related device, designed to be used alone or with other human devices, for one or more of the following purposes:

1- Diagnosis, prevention, monitoring, treatment, or alleviation of disease.

2- Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury.

3- Investigation, replacement, modification, or support of the anatomy or of a physiological process.

4- Supporting or sustaining life.

5- Control of conception.

6- Disinfection of medical devices.

7- Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body.

B) Devices that cannot achieve their true purpose for which they were designed without pharmaceutical drugs, immune agents or metabolic shunts, but only help to achieve their effects.

**Medical devices accessories and products:** The products that are specifically manufactured for use with a medical device to enable the device to achieve its intended purpose.

**Fully refurbished medical devices and products:** The used medical device that has been updated to function as the new device and is subject to the same requirements for conforming to the new device.

**In vitro diagnostic medical devices and products:** means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

**Establishment** Any legal entity that carries out an activity in the Kingdom related to medical devices and products, such as their manufacture, use, marketing, distribution, or representing the manufacturer in marketing or distributing them.

**Manufacturer:** Any natural or legal person with responsibility for designing and manufacturing the medical device and product for the purpose of introducing it for use under their name, whether the medical device and product are designed or manufactured by the person themselves or by another person on their behalf.

**Authorized representative:** The person authorised in writing by the manufacturer to represent the manufacturer before the authority in accordance with specific tasks, such as representing the manufacturer before the authority.

**Importer:** The first person in the supply chain to import the medical device and product to the Kingdom.

**Distributor:** The first person in the supply chain to deliver the medical device and product to the end user.

**Medical Devices and Products Record:** A database of medical devices and products and the establishments used for them.

**Medical Devices and Products Reporting Center:** A system for managing the database of information relating to the safety and performance of medical devices and products and for taking appropriate procedures on reports.

**Marketing the medical device and product in the market:** Providing a new or completely refurbished medical device and product in the Kingdom, whether free of charge or exchange for payment, for distribution or use.

**Use of the medical device and product in service:** The stage in which the medical device and product are provided to the end user with the aim of using them in the Kingdom to perform the purpose for which they were made.

**Advertising for medical devices and products:** Any statement, whether written, read, audible, visual, or otherwise, for the purpose of promoting, selling, or marketing medical devices and products.

**The Verification Office** An office for verifying the compliance of medical devices and products with the requirements approved by the regulatory authority. It operates as a third-party entity located in the Kingdom and is independent of the manufacturer and user of the medical device intended for evaluation.

**Article (2)**

This decision aims to protect public health in the Kingdom by implementing procedures and requirements that ensure the protection of the health and safety of patients, the public, and users of the medical device and product in order to ensure the safety of medical devices and products during the stages of their manufacture, marketing, and use by taking measures and determining the responsibilities necessary to ensure the conformity of the medical devices and products offered in the Kingdom to all standards and requirements of this Decision.

**Article (3)**

The provisions of this Decision shall apply to all Health institutions that use medical devices and products, laboratory and diagnostic devices, manufacturers and their authorized representatives, importers, and distributors, in addition to all medical devices and products that shall be marketed in the Kingdom, such as contact lenses and lasers used for non-surgical cosmetic purposes and their accessories.

**Article (4)**

The Authority monitors the use of medical devices and products in the Kingdom and takes the necessary and appropriate procedures to ensure the safety of their use and maintenance in order to ensure the safety of patients, the public, and users of the medical device and product. The Authority shall notify patients or users once it is confirmed that the medical device or product is not complying with the provisions of this Decision.

**Article (5)**

The Authority establishes an electronic system for the registration of medical devices and products and their establishments, in which all data relating to the device and the establishment, in particular the name of the device, serial number, country of origin, and shelf life, shall be recorded as follows:

1- Inventory and management of the information required to register medical devices and products and their establishments.

2- A visualization of the market size for medical devices and products in the Kingdom.

3- To provide information on establishments involved in the manufacture or supply of medical devices and medical products in the Kingdom.

4- Provide information on medical devices and products that will be marketed or are already used in the Kingdom.

**Article (6)**

Importers, distributors, manufacturers, and authorized representatives of manufacturers engaged in the supply or distribution of medical devices and products shall obtain a license from the Authority.

**Article (7)**

The device and medical product shall be used in healthcare establishments licensed by the Authority, and it is not permissible to manufacture or introduce any medical device and product to the Kingdom or put it in its markets, or use it, except after registering with the Authority and obtaining written permission to market from the Authority. and it is not permissible to transfer, resell, dispose of, or export any medical device and product without the written approval of the Authority.

**Article (8)**

All health establishments shall obtain an Authority permit to use medical devices and products before using them.

**Article (9)**

All importers are obliged to ensure the storage and transportation of the medical device and product in accordance with the instructions described in the manufacturer's recommendations attached to the medical device or product, and in case of non-compliance, the Authority may revoke the registration of the medical device or cancel the license of the importer.

**Article (10)**

It is forbidden for any person to market or advertise the medical device and product unless they obtain a license from the Authority.

The marketing license for medical devices and products that comply with international quality and safety standards shall be valid for (12) months or until the expiration of the quality certificate of the device or product, whichever is earlier.

The advertising license for medical devices and products is in accordance with international quality and safety standards. and the license is deemed to be cancelled in the event of a change in any pre-approved advertising content.

**Article (11)**

The Authority reviews and checks the communications received by its Medical Devices and Products Reporting Centre and takes the necessary procedures to ensure the safety of public health, and when needed, promulgates field safety alerts to educate users of the medical device and product to the relevant patients. It also reviews the text and content of the alerts with the medical device and product manufacturer or authorized representative before promulgating the alert.

**Article (12)**

The Authority may withdraw or prohibit the use of any medical device or product where it appears to it that it may endanger the health or safety of patients and users.

**Article (13)**

Subject to Article (7) of this Decision, all establishments shall dispose off medical devices and products in accordance with the requirements, and medical devices and products may not be used beyond their shelf life.

**Article (14)**

The Authority may delegate some of the tasks referred to in this Decision to the Conformity Assessment Body, while the Authority continues to be responsible for those tasks.

**Article (15)**

The Authority shall take all necessary legal procedures when violating any of the provisions of this Decision.

**Article (16)**

The Chief Executive Officer of the Authority promulgates the requirements, controls, procedures, standards, and decisions necessary to implement the provisions of this Decision.

**Article (17)**

Fee categories are calculated based on the services and requests referred to in the provisions of this Decision, which aim at reviewing and evaluating to ensure the quality of health services and performance levels.

**Article (18)**

The Chief Executive Officer of the Authority of the National Health Regulatory Authority for Regulating Health Professions shall implement the provisions of this Decision, and it shall come into force on the day following the date of its publication in the Official Gazette.

**President of the Supreme Council of Health**

**Lieutenant Doctor/ Mohammed bin Abdullah Al Khalifa**

promulgated on: 14 Jumada Al-Awwal 1442 A.H.

Corresponding to: 29 December 2020