Resolution No. (48) of 2020
On Medical Devices and Products' Quality Control

Chairman of the Supreme Council of Health:
The National Health Regulatory Authority

After perusal of Decree-Law No. (2) of 1987 regarding non-physicians and pharmacists practicing allied health professions,
And Decree-Law No. (7) of 1989 regarding practicing the profession of medicine and dentistry,
And Law No. (38) of 2009 Establishing the National Authority Regulatory Authority, as amended by Decree-Law No. (32) of 2015,
And Decree-Law No. (21) of 2015 regarding private health facilities, as amended by Law No. (1) of 2019,
And the Health Insurance Law No. (23) of 2018,
And the Public Health Law No. (34) of 2018,
And Decree No. (5) of 2013 establishing the Supreme Council of Health, and its amendments,
And Resolution No. (2) of 1977 regarding the health specifications, requirements and equipment that must be available in private doctors' clinics,
Resolution No. (21) of 1987 regarding licensing procedures for the establishment and management of a private hospital,
Resolution No. (22) of 1987 regarding health, technical and safety requirements that must be met in private hospital facilities and equipment,
And Resolution No. (3) of 1995 regarding the conditions, specifications and medical equipment that must be available to authorize doctors to open private clinics for 24 hours and in official holidays, as amended by Resolution No. (1) of 2003,
Resolution No. (1) of 2001 regarding the management of hazardous waste for health care,
And Resolution No. (3) of 2014 regarding the regulation of medical centers,
Resolution No. (4) of 2014 regulating radiological applications in health facilities,

And Resolution No. (20) of 2016 regarding defining fee categories for private health facilities,
Resolution No. (24) of 2016 issuing a list of allied health professions,
Resolution No. (2) of 2019 regarding classification of health facilities, health and technical requirements, and safety requirements that must be met in their premises and equipment,
And after the approval of the Supreme Council of Health,
And based on the proposal of the CEO of the National Health Regulatory Authority,
It was decided:

Article (1)
Definitions

Upon applying the provisions of this regulation, the following words and expressions shall have the meanings assigned to each of them:
Kingdom: The Kingdom of Bahrain.
The Authority: The National Health Regulatory Authority.
Person: A natural or legal person.
Medical device and products:
Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article:

A) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose (s) of:
   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;

and

B) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Medical device accessories and products means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use.

Fully refurbished medical device and product: 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.

Invitro diagnostic medical devices and products (IVD): 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.

Facility: 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 person1 with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Authorized representative: Any natural or legal person established within the kingdom who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

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

Distributor: Any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

1 The term "person" that appears here includes legal entities such as a corporation, a partnership or an association.

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

Medical Devices and Products reporting Center: A system for managing the database of information related to the safety and performance of medical devices and products and taking appropriate actions regarding safety and quality reports.

Marketing the medical device and product in the market: providing a new or completely refurbished medical device and product in the Kingdom for free or for a fee, whether 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 it in the Kingdom to perform the purpose for which it was 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.

Conformity Assessment Body (CAB): A body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorized to undertake specified conformity assessment activities by a Regulatory Authority that will ensure performance of the CAB is monitored and, if necessary, withdraw designation.

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 for all standards and requirements of this decision.

Article (3)

The provisions of this decision shall apply to all health facilities 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 will 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 measures 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, and the authority shall notify patients or users once it is confirmed that the medical device or product is/are not complying with the of the provisions of this decision.

Article (5)

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

- Inventory and management of the information required to register medical devices and products and their facilities.
- A visualization of the market size for medical devices and products in the Kingdom.
- Provide information on facilities engaged in the manufacture, distributors or importers medical devices and products in the Kingdom.
- Provide information on medical devices and products that will be marketed or 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 must obtain a license from the Authority.

Article (7)

The device and medical product must be used in healthcare facilities 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 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 facilities must take 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 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 obtaining 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 expiry 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 of any pre-approved advertising content.

Article (11)

The Authority reviews and checks the communications received by its Medical Devices and Products reporting Center and takes the necessary measures to ensure the safety of public health, and when needed issues field safety notices to educate users of the medical device and product to the relevant patients, and also review the text and content of the alerts with the medical device and product manufacturer or authorized representative before issuing the alert.

Article (12)

The Authority withdraws or prohibits the use of any medical device and product when it appears that it may endanger the health or safety of patients and users.

Article (13)

Subject to article (7) of this decision, all facilities must dispose of 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 contained in this resolution to the Conformity Assessment Body (CAB), while the Authority continues to be responsible for those tasks.

Article (15)

The Authority shall take all necessary legal measures when violating any of the provisions of this decision.

Article (16)

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

Article (17)

Fee categories are calculated for the services and requests that aim to review and evaluate stipulated in the provisions of this resolution, to ensure the quality of health services and performance levels.

Article (18)

The Chief Executive Officer of the National Health regulatory Authority must implement the provisions of this decision, which will be implemented from the day after the date of its publication in the Official Gazette.

President of the Supreme Council of Health
Team Doctor Mohammed bin Abdullah Al Khalifa

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Corresponding: December 28, 2020