Resolution No. (24) for 2021
Amending some provisions of Resolution (20) for 2016
on the definition of fees for private healthcare facilities

Minister of Health:

After reviewing Law No. 38 of 2009 with the establishment of the National Health Regulatory Authority, amended by Decree No. (32) of 2015،

and the decree - Law No. (21) of 2015 regarding private healthcare facilities, amended by Law No. 1 of 2019, and in particular Article (28) of it,

and Decree No. (5) of 2013 for establishing the Supreme Council of Health and its amendments,

and resolution (20) for 2016 on the definition of the categories of fees for private healthcare facilities,

and Resolution (48) of 2020 on the control of the quality of medical devices and products, in particular article (17) of it,

Based on the proposal of the Supreme Council of Health,

After cabinet approval,

It was decided,

Article 1

To add table (3- Table of services and requests for medical devices and products) attached to this decision on the services and requests of medical devices and products at the National Health Regulatory Authority, to the tables listed in article (1) of resolution (20) for 2016 on the categories of fees of private healthcare facilities.

Article 2

The Chief Executive of the National Health Regulatory Authority must execute this decision, and it should be implemented a month after it is published in the national gazette.

Minister of Health
Faeqa Saeed Al-Saleh

Issued on 17 Rajab 1442 E
Correspondence to 1st of March 2021

(3) Schedules of services and requests for medical devices and products in the National Health Regulatory Authority

Table #1Medical devices Authorized representative Licensing services

Service Type	Item	Type	Fees (Dinar Bahraini)	Norm
License Application fee			50	Each new order
Authorized Representative licensing	Class A	First license	1,000	First license
		License renewal	700	Annual
	Class B	First license	700	First license
		License renewal	500	Annual
	Class C	First license	500	First license
		License renewal	300	Annual
	Class D	First license	300	First license
		License renewal	200	Annual
Medical devices Warehouse licensing			1,000	First license
			800	Annual
Medical devices manufacturer licensing			5,000	First license
			3,000	Annual
Update medical device facilities data			50	Each request
Re-inspection of medical device facilities			50	Each request

Table #2 Medical device registration services

Service Type	Item	Type	Fees (Dinar Bahraini)	Norm
Request to submit a registration request			5	Each new device
Medical device registration	Low risk	First registration	150	Annual per license
		Registration renewal	100	Annual per license
	Medium risk	First registration	300	Annual per license
		Registration renewal	200	Annual per license
	High risk	First registration	1,000	Annual per license
		Registration renewal	700	Annual per license
Update medical device registration data			20	Each device

Table #3Medical devices importation services

Service Type	Item	Type	Fees (Dinar Bahraini)	Norm
Request approval to import a single device	Medical device	Registered	0.5	Each type
		Unregistered	2	Each type
	IVD/combined medical device	Registered	1	Each type
		Unregistered	3	Each type
Verify the validity of the quality certificate			5	Each type
Product classification request		regular	20	Each type
		Urgent	40	Each type
Demurrage for the device till approval			100	Per day
Issuing a product classification certificate			15	Each certificate
Sample examination			5	Each type
Inspecting the shipment at the port			10	Each type

Table #4 Other services

Service Type	Item	Type	Fees (Dinar Bahraini)
Permit to use	Submit a request for approval to use the device	0.5	Each device
	Evaluate the viability of the product	50	Each device
Issuing certificates for medical manufacturer and devices, free sale and other paper documents		10	Each request
Product disposal supervising		25	Each request