29th March 2022

# HEALTHCARE

## Further Regulation of Medical Devices in Kuwait – Ministerial Decree No. 13 of 2022.

The use and interest in e-health solutions and medical devices which provide for ease of access and responsiveness to patients' wellness and daily healthcare needs continues to grow at pace with an increasing variety of new offerings in the market. In essence, these solutions and devices can provide much needed diagnosis and preventative tools and measures in the monitoring and fight against sickness and can be aligned to other treatment and investigations in and out of hospitals.

As a dynamic area with continuous and fast developing solutions to care, with the potential for complexity and different medical purposes and levels of risk, it has attracted considerable legal and regulatory attention worldwide and frameworks to address the use and marketing of the medical devices. Medical devices can be used as an alternative to physical assessments and other more typical testing methods. For example, the use of the developed devices to measure and keep track of blood glucose in the human body.

The law and regulation need to embrace the innovations but also provide for necessary review and approval of the devices for sale and marketing.

## New Ministry of Health Regulations

In Kuwait, the regulation of such medical devices is subject to the oversight and supervision of the Ministry of Health ("**MOH**").

By way of Ministerial Decree No.13 of 2022 ("**Decree**"), the Ministry has implemented new regulations for the registration and release of medical devices in Kuwait. These requirements came into effect on 23rd January 2022 and apply to every device that falls under the definition of a 'medical device'.

These new regulations are a further step in the regulation of the sale and marketing of medical devices and follow earlier regulation of the MOH relating to registrations. The new regulations are significantly more detailed and the introduction of them not only acknowledges the significance

and fast-growing developments in the use of such devices for multiple purposes in healthcare, but they ensure more alignment to international regulation and standards, such as the EU Medical

Devices Regulation[1], and provide more transparency and risk assessment relating to those devices through the registration requirements.

Without registration, the devices cannot be imported, marketed and sold in Kuwait.

## What is Considered as a Medical Device?

The regulation focuses on the purpose of the devices. Under Article 1 of the Decree, a medical device is defined as "any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- Providing information by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;
- Disinfection substance for medical devices or medical instruments;
- Aids for persons with disabilities;
- Devices incorporating animal and/ or human tissues;
- Devices for in *vitro* fertilization or assisted reproduction technologies;
- Devices for cosmetic/aesthetic."

## Classification of Devices

The Decree highlights in Article 4 that the registration and regulatory assessment of the particular devices will be based on levels of control commensurate to "the level of potential hazard inherent in the type of medical device concerned". The hazard presented by a particular medical device fundamentally depends on its intended use and the technology it utilizes.

Medical devices are further classified by rules into four tiers, corresponding to EU Medical Device Regulation[2], (with very detailed examples provided to assist decisions as to the classifications)

[1] European Union Medical Device Regulation (2017/745).
[2] European Union Medical Device Regulation (2017/745).



Al Hamra Business Tower, 58th Floor, Sharq, Kuwait City. P.O.Box 20941, Safat 13070, Kuwait
TEL 00965 2 220 5344 FAX 00965 2 220 5341 E-MAIL icb@icbkuwait.com.kw
icbkuwait.com.kw

aligned to the above principles and the degree of risk and hazard that the particular device may cause to the individual. Class A represents the lowest hazard and Class D represents the highest.

## Compliance by Manufacturers

Manufacturers of devices must demonstrate compliance to essential principles of safety and performance in the regulations as part of the submission of detailed information in support of applications to MOH for registration. The manufacturer must further follow the classification rules set out in the regulations and make an independent decision on classification of the device taking account of its particular design and intended use.

## Requirements of Registering Medical Devices in Kuwait:

Before any marketing of the medical devices in Kuwait, they must have been registered by the agent or distributor of the manufacturer with the Pharmaceutical & Herbal Medicines & Registration & Control Administration department of MOH.

There are detailed requirements for registration set out in the Decree regulations. These requirements include administrative documents, information regarding the medical device, device labelling, declarations of conformity from the manufacturer and important information required on how the manufacturer has met the essential principles of safety and performance (including past recall information) and other applicable information depending on the device. Sampling and analysis of the device under laboratory may also be required.

The information for registration must cover information relating to the local agent, manufacturer and factory (if separate). There are general requirements for all devices but additional requirements for further types of information required commensurate with the potential hazard which is aligned to the classification of the device (Class A to D), as referred to earlier.

For example, applications for registration of Class C devices must include information on clinical studies confirming the effectiveness and safety of the product issued by accredited bodies as well as particular specifications for the outer packaging and the inner leaflet provided by the manufacturer for its use. For Class D (devices used for more invasive application), there must also be a file provided containing all steps followed in the control over essential raw materials during the assembly, manufacturing and storage process including certificates confirming the device is free of viruses that might cause infectious diseases.

After registration is confirmed, the MOH will issue a certificate of registration (valid for 5 years) and this can be used with pharmacies or medical centres to market and sell the devices.



Al Hamra Business Tower, 58th Floor, Sharq, Kuwait City. P.O.Box 20941, Safat 13070, Kuwait
TEL 00965 2 220 5344 FAX 00965 2 220 5341 E-MAIL icb@icbkuwait.com.kw
icbkuwait.com.kw

The regulations also provide for renewal and cancellation of registrations as well as requirements for the transfer of agency to a new local agent. A device is liable to cancellation if the appointed agent fails to renew the device registration.

## Cost and complexity but important steps forward

The implementing regulations are detailed and require significant amounts of information and documentation in support of applications for registrations. This includes legalization and attestations of required foreign documents, all of which affects time and costs.

These legal requirements are on top of other access and distribution requirements for manufacturers that must put in place effective commercial agency or distribution agreements with local Kuwaiti agents or distributors under applicable laws and also within the constraints and requirements of tendering including Kuwait Public Tender Law No. 49 of 2016 and its amendments.

The registration of the devices and the requirements for safety considerations and classification by risk are also indicative of increasing concerns to safeguard hospital and primary healthcare operators and patients in the availability and use of such devices, particularly used in a more invasive capacity. Manufacturers and distributors must also be aware of other Kuwaiti laws on consumer protection, product recalls and general liability under civil and commercial laws in the offering and use of the devices. It is a complex area and one likely to see further changes of law and regulation given innovation, use of technologies and applications, more sophistication, its dynamic nature and the growing importance of such devices in the delivery of healthcare.

For any further detail on the registration requirements or clarifications or advise regarding this briefing or on the applicable law and regulation relating to medical devices, please contact key persons in ICB's team specializing in Healthcare below.

# Contacts:

Aisha Alnesef: aisha.alnesef@icbkuwait.com.kw
Roger Phillips: roger@icbkuwait.com.kw
Yousef Al Anjeri: y.alanjeri@icbkuwait.com.kw
Mohammad Marzouq: Mohammad.marzouq@icbkuwait.com.kw