



## IN THE NEWS

### Guidelines for Medical Devices in the UAE Healthcare Industry

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Healthcare is among the priority sectors identified by the UAE government and as a result, the UAE healthcare industry has displayed extraordinary growth and significant progress in the past few years. In line with the UAE government's focus to improve the standard of healthcare, each year the UAE hosts the largest healthcare event in the region - the Arab Health. The Arab Health provides the perfect business platform for healthcare companies to showcase their products and enter into business relationships with health and medical institutions. This year's Arab Health took place in January and attracted over 3,000 exhibitors from 60 countries and more than 65,000 healthcare professionals worldwide.

Given the tremendous success of the event, it is expected that many foreign companies will be entering into the UAE healthcare market either through distributorships and agencies or by setting up legal entities in the region. However, prior to supplying any medical devices in the UAE, it is crucial that foreign companies register their products with the relevant authorities. This article reviews the primary features of the regulatory guidelines for medical devices in the UAE and how it might affect medical device companies that are contemplating doing business in the region.

#### **Ministry of Health Guidelines**

Medical devices are regulated by the Ministry of Health which has enacted certain guidelines for the registration of medical products. The guidelines are intended to prevent unsafe or ineffective medical devices from entering the marketplace while providing the public with timely access to them. According to these guidelines, medical device manufacturers must register their products before they can market them in the UAE.

The Ministry of Health has labored hard to ensure the highest international standards in developing the criteria for medical device registration. Furthermore, the registration guidelines were designed to simulate internationally recognized rules and regulations; mainly the EU Medical Device Directive (93/42/EEC) and U. S. Food and Drug Administration Guidelines.

### **Registration of Medical Devices**

These guidelines set out the exhaustive requirements to register medical devices. An application to register a medical device in the UAE must be made by the device manufacturer or its local representative. The local representative must be formally authorized by the manufacturer to handle the application process and the manufacturer's legal obligations and responsibilities with regard to entering the medical device in the UAE marketplace. These guidelines broadly provide four classes of medical devices for the purposes of registration. This classification system takes into account aspects such as the how long the medical device is intended for use, and the degree of invasiveness on the body. Depending on the classification of the medical device in question, and the information available with regard to approvals by regulatory bodies in other countries, the Ministry of Health considers an application for registration through either a one or a two stage process. The application must also be supported by the submission of objective evidence relating to the safety and effectiveness of the medical device. The registration guidelines also list the information required to be submitted in order to be considered for registration. In addition to the application, several supporting documents are required to be submitted including prior approval from recognized regulatory agencies such as those in Europe, the U. S., Australia, Canada or Japan. If the safety and effectiveness of the medical device is established and the Ministry of Health approves the registration, a certificate of registration is granted which permits the importation and sale of the registered medical device in the UAE. The registration is generally valid for five years.

### **Post-Market Obligations**

As the key purpose of registering medical devices is to ensure safety, the guidelines also provide for post-market obligations with regard to monitoring, and preparing for safety issues that may arise in the marketplace. The post market obligations include the following:

1. Maintaining distribution and complaint handling procedures records.
2. Maintaining adverse incident reporting procedures and records.
3. Having procedures to promptly and effectively execute investigations and recalls of defective or potentially defective medical devices.

## **Conclusion**

The healthcare industry in the UAE is quickly expanding, resulting in foreign players to leverage opportunities offered in the region. Whether a foreign company decides to supply healthcare devices through a distributor or set up their own operations, it can sometimes be difficult for foreign entrants to meet regulatory requirements for medical devices. Before mistakes are made, these businesses should consult with a law firm that can assist in all phases of healthcare regulation, particularly in respect to advice relating to registration of medical devices.