United Arab Emirates

World Bank income group: High income

Legal

Legal framework: Yes

Authorizing legislation: Pharmaceutical Profession and Institutions, Federal Law No. 4 (June 1983)


National Regulatory Authority

National Regulatory Authority present: Yes

Name: Ministry of Health http://www.cpd-pharma.ae/index.php

Responsibilities of the NRA: Medical Device control and regulation in UAE will be supervised and directed by Drug, Control Dept / MOH. http://www.cpd-pharma.ae/downloads/4-Medical%20Device/MD%20guide%20line.pdf

Medical device definition

Medical device defined: Yes

Text: A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article-a) intended by the company and its manufacturing site to be used, alone or in combination, for human beings for one or more of the specific purpose(s) 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,
- Indicate the sterilization process completion
- 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 Registration Guideline, pg. 7-8.

In vitro diagnostic medical device (IVD) defined: N/A

Text: N/A

Medical device classification

Classification: Yes


Classification rules: Yes

Classification rules details: Specific classification rules are detailed in Annex 1 of the Medical Device Registration Guideline. 5.2, p. 20.

Additional considerations for classification include:
- the intended purpose assigned by the manufacturer determines the class of the device
- if a device may be classified according to more than one class, then the highest class applies
Medical Device Registration Guideline, 5.4, p. 20-21.

In-Vitro Diagnostic medical devices are classified into 4 classes: Class A, B, C, D (based on the potential risk involved in their use and interpretation clinically)
Medical Device Registration Guideline 5.3, p.20 - See Annex 2 for rules

Essential principles

Essential principles: Yes

Details: N/A

Conformity assessment

Conformity assessment bodies: Yes

Details: Yes

Conformity Assessment bodies must fulfill requirements of EN45000 series and ISO/IEC 17025.
Medical Device Registration Guideline, 4.1, p. 17.

Pre-marketing / procedure: Medical device companies must undertake conformity assessment according to essential principles. In some cases, depending on the class of the device, technical documentation and approval of the foreign notified body may be reviewed before the device may be placed on the market. Medical Device Registration Guideline, 6, p. 21.
**Reliance**
Reliance: Yes  
Details: N/A  
Jurisdictions: EU, Austria, Canada, US, Japan, Singapore  
Medical Device Registration Guideline, 4.2, p. 17-18.

**Clinical investigation**
Clinical investigation controls: N/A  
Details: N/A

**Registration and listing**
Registration of establishment: Yes  
Details: Yes - A company must register with the Ministry. Medical Device Registration Guideline, 8, p. 23.  
Listing of medical devices: Yes  
Details: A company must submit registration at the same time it submits registration for its first product. See Medical Device Registration Guideline, p. 12.

**Import controls**
Import controls: Yes  
Details: Imports of medical devices are subject to a pre-importation process; however, there are some exceptions. Medical Device Registration Guideline, 2.1, p. 15.

**Post market controls**
Post Market Surveillance: Yes  
Details: Manufacturers and local authorized representatives must keep records on safety of the device, including complaints and perform corrective action. Medical Device Registration Guideline, p. 29.  
Inspection (QMS): N/A  
Details: N/A  
Enforcement: N/A  
Details: N/A  
Adverse event reporting: Yes  
Details: Importation - The local representative for a manufacturer must monitor the device placed on the market and inform the Authority of any adverse event. Medical Device Registration Guideline, 3.5, p. 16-17.  
Manufacturers - Manufacturers and local authorized representatives are required to notify the Drug Control of any adverse events related to a failure of the device or a deterioration of its effectiveness or any inadequacy of Labelling or directions for use that has resulted in death or deterioration of health. Medical Device Registration Guideline, p. 29.  
Field safety corrective action monitoring: N/A  
Details: N/A  
Advertising: N/A  
Details: N/A  
Labelling: Yes  
Details: Importation - All medical devices must bear a clear label that includes the name of the company responsible for the placement of the product in the UAE, the manufacturer in the originator country, the local distributor’s address or website. Medical Device Registration Guideline, 2.4, p. 16.  
Manufacturers - Labels must be visible on the outer package and legibile. Medical Device Registration Guideline, p. 31.

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.