Legal

Legal framework: Yes
Authorizing legislation: Medical Device Regulations (31 Aug. 2010)
http://www.eda.mohealth.gov.eg/Articles.aspx?id=46
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Medical Device Department, Egyptian Drug Authority http://www.eda.mohealth.gov.eg/Articles.aspx?id=121

Responsibilities of the NRA: The Egyptian Drug Authority (EDA) is “an initiative for” an organization within the Ministry of Health that is responsible for safeguarding people health by regulating safety and quality of medicines (human and veterinary), biologicals, medical devices, cosmetics, dietary supplements and pesticides. The Medical Device Safety Department (MDSD), within the Central Administration of Pharmaceutical Affairs (CAPA), is a separate entity slated with monitoring the medical device market in Egypt.

Medical device definition

Medical device defined: Yes
Text: A medical device is any medical device or machine tool application of medical or medical use, whether alone or with any other supplements such as those required for special applications are running, which developed for human use of the following goals and targets:
- Diagnose, prevent, or control or cure or mitigation of disease analgesia.
- Diagnosis, control or cure or mitigation of analgesia or compensation for any disability or disability.
- Check or compensation or to improve the work of Physiology and autopsy.
- Prevent pregnancy.
Such as:
- Devices that are running through a power source.
- Devices planted the human body, and self-working power source.
- Purpose-designed equipment for specific purposes.
- Devices designed for clinical studies.
- Hardware diagnostic test.
And which cannot be achieved through:
- Medical drugs.
- Immune serum.
- Metabolism.
http://www.eda.mohealth.gov.eg/Articles.aspx?id=127

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

Medical device classification

Classification: Yes
Classification rules: Yes
Classification rules details: N/A

Essential principles

Essential principles: N/A
Details: N/A

Conformity assessment

Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: Yes - Depending on the risk class of the device, the conformity assessment procedure varies. (E.g., A Class I non-sterile, non-measuring device requires a declaration of conformity before it may be placed on the market.) http://www.eda.mohealth.gov.eg/Articles.aspx?id=127
Reliance
Reliance: Yes
Details: Egypt relies on the highest health authority to issue a certificate of free circulation. This Free Sale Certificate is necessary for any product. http://www.eda.mohealth.gov.eg/Articles.aspx?id=127
Jurisdictions: USA, EU

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

Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: N/A
Details: N/A

Import controls
Import controls: N/A
Details: N/A

Post market controls
Post Market Surveillance: Yes
Details: The manufacturer must collect data in one of two situations: (1) as a condition of product approval, and (2) to re-affirm product safety when post-market adverse incident reports suggest that pre-market safety claims are inconsistent with actual use and result in unacceptable risk. Guideline for Medical Device Vigilance System, pg. 5.

Inspection (QMS): Yes
Details: The department of medical device inspection conducts the following types of inspection on medical devices local manufacturers aiming to insure that they apply GMP regulations:
- Initial
- Periodic (routine inspection)
- Unannounced
- Special
In addition, the department inspects stores of imported medical devices. http://www.eda.mohealth.gov.eg/Articles.aspx?id=109

Enforcement: N/A
Details: N/A

Adverse event reporting: Yes
Details: The manufacturer must:
- have suitable vigilance systems in place,
- Notify the Medical Device Safety Department (MDSD),
- investigate and assess incidents,
- submit a trend report to the MDSD when reporting criteria are met as well as a periodic summary report.
Guidelines on a Medical Device Vigilance System, pg. 7.
Users are also encouraged to report suspected incidents to the manufacturers. Guidelines on a Medical Device Vigilance System, Art. pg. 27.

Field safety corrective action monitoring: Yes
Details: Manufacturers must notify the MDSD of any Field safety corrective actions (FSCA) of their products, take all necessary corrective actions, issue a field safety notice, and distribute that notice to organizations and users. Guidelines on a Medical Device Vigilance System, pg. 7.

Advertising: N/A
Details: N/A
Labelling: N/A
Details: N/A

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.