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Have you ever thought of getting rid of diseases that affects your life without any medical device? It seems impossible as doctors canâ€™t treat a patient without them and thatâ€™s why its relevance canâ€ ignored. These medically certified devices have brought about a revolution in the field of medical sciences. These medical equipments are very important to decrease the mortality rate.

In this article, we will talk about medical devices, classification of medical devices in Italy, and the need of medical consultants for medical devices.

Medical Devices

Medical devices are also known as pharmaceuticals. These are well-tested appliances which are used for medicinal purposes like therapy, surgery or diagnosis. Various means of actions of medical devices include physical, pharmacological, mechanical, thermal, metabolic, immunological, physico-chemical or chemical etc.

Medical industry has a vast array of products or equipments varying in apps and intricacy. For instance medical thermometers, blood sugar meters, dialysis machines, infusion pumps, medical lasers, CT scanners, tongue depressors, heart-ling machines, ECMO, medical ventilators, ultrasound and MRI machines, anesthetic machines, X-ray machines, PET scanners, etc.

The international market of medical devices growing tremendously and according to a survey it has reached approx. 209 billion US dollar in the year of 2006.

Classification

Before introducing medical devices to the open market, they have gone through the classification process to avoid any risks, misuse or adverse effects on human health. The task of classification is executed by the regulatory authorities. The regulatory authorities distinguish diverse classes of medical devices Italy based on their design complexity, attributes, and intensity of their harm on human health, if they are misused or not used properly.

The regulatory and monitoring authorities give approvals to products coming with effective and safe to use features, thus, medical device manufacturers keep such things in consideration.

Classification of medical devices in Italy

The categorization of medical devices in Italy is done into four classes, ranging from low risk to high risk.

â€¢ Class I (including Is & Im)

â€¢ Class IIa

â€¢ Class IIb

â€¢ Class III

The approval of medical devices is guaranteed by a Declaration of

Conformity. The manufacturer itself assured the authorization of these medical products, but for devices in Class Is, Im, IIa, IIb or III, must be verified by a Certificate of Conformity that is issued by a Notified Body.

If the products are meeting European Directives, it means products of

manufacturers are 100% safe & are following the harmonized standards.

Certified medical devices with MD directives must contain CE mark, harmonized pictograms and EN standardized logos on packaging to indicate necessary points like expiry date, manufacturer, instructions for use, sterile, No reuse etc.

Before introducing medical devices of any of the above mentioned classes in the pharmaceutical market, these equipments need to get registered effectively with the help of professional medical device consultants as registration illustrates that they are user-friendly, safe, secure and effective.

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Arazy Group - About Author:
Arazy Group has been serving Middle East, Europe, Latin America, Africa, Asia, etc, with advanced a medical device consultancy services for different class of medical devices. To get guaranteed registration of a medical devices in Italy, customers can take help of this renowned firm.

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