Malaysia Medical Device Regulations

In Malaysia, general medical and IVD devices are regulated by the Medical Device Authority (MDA) of the Ministry of Health. The regulatory framework is based on the Medical Device Act 2012 (Act 737) and Medical Device Regulations 2012 and closely follows GHTF guidelines. Foreign manufacturers (outside Malaysia) must appoint an in-country Authorized Representative (AR) to manage device registration and to authorize an importer and distributor to import and supply devices post approval.

International standards shall be widely used to demonstrate conformance to essential principles of safety and performance of a medical device as well to show compliance with process, product and management requirements. International standards are building blocks for harmonized regulatory processes and their use is essential in simplifying the regulatory process and promoting global harmonization efforts.

The definition of medical device is in accordance with the global harmonized (GHTF) definition which covers any products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs. All medical devices carry certain level of the associated risks which depend on the intended purposes and the effectiveness of the risk management techniques during design, manufacture and use. Based on a set of rules, medical devices are classified into four risk classes. In general, low-risks devices are those that are applied external to the body; and if applied correctly, involve minimum risk to the patients. The higher risk devices are those that penetrate the human body, and involve a high-energy source, or used to sustain life.

For further info, please browse to **Medical Device Authority, Ministry of Health Malaysia** website at http://www.mdb.gov.my