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MEDICAL DEVICE REGISTRATION REQUIREMENTS UNDER THE ACT 737

Mariammah Krishnasamy*

Medical Device Authority, Ministry of Health, Cyberjaya, Selangor, Malaysia

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*Corresponding Author:
Mariammah Krishnasamy
Email:
mariammah@mdb.gov.my

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SUMMARY

Medical Device Registration requirements: Act 737 and MDR 2012 consists of 80 sections and is divided into six parts and MDR 2012 consists of 22 regulations, 6 schedules and is divided into 9 parts

Medical device regulatory system is intended to ensure protection of public health and safety. It is based on the safety and performance of medical devices throughout their life cycle. Essentially, prior to placing a medical device into the market, conformity assessment is conducted to provide objective evidence of safety, performance and benefits and risks to maintain public confidence

Registration with the Medical Device Authority (MDA) is done electronically through the web-based Medical Device Centralized Online Application System (MeDC@St) and can only be done by the local Authorized Representative.