

6 PHASES OF MEDICAL DEVICE LIFECYCLE



01

Initial evaluation of possible development of a medical device



02

Definition of design input based on customer needs and technical requirements



03

Development of product design and of the manufacturing process, verification and validation



04

Final validation of the manufacturing process and preparation for product introduction



05

Regulatory approval, IECs & Clinical testing, Launch the product to market, Individual country reimbursement approval



06

Post Market Surveillance, Post market clinical follow-up, Complaints, and Adverse Events, Product improvements, External body audit, Market performance, New market launches

Medical Device Software Software Life Cycle Processes

Malaysia. Jabatan Standard



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