Category 1 changes of medical devices that affect their safety and performance and require new registration of the medical device

For category 1 changes, the following types of changes require the registration holders to apply for new registration.

a) Change to the intended purpose (e.g. new and additional) of a registered medical device, unless it involves a reduction of indications for use not arising due to medical device safety and/or performance concerns;

b) Change to the risk classification of a registered medical device;

c) Addition of devices not considered a permissible variant according to the rules of grouping in Second Schedule of MDR 2012 and MDA/GD/0005, Product Grouping;

d) Addition of variant(s) for Cluster (Class A and B) according to the rules of grouping in Second Schedule of MDR2012 and MDA/GD/0054 Product Grouping for In- Vitro Diagnostic (IVD) Medical Devices;

e) Change to the type, concentration or drug specifications (DS) of medicinal substance in a medical device that incorporates a medicinal product as an ancillary role shall be refer to National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia; and

f) Addition of medical devices with device proprietary names different from the registered devices, into a device listing. Unless the devices with different proprietary names qualify to be listed together under one listing based on MDA guidance documents on grouping criteria for medical devices registration.