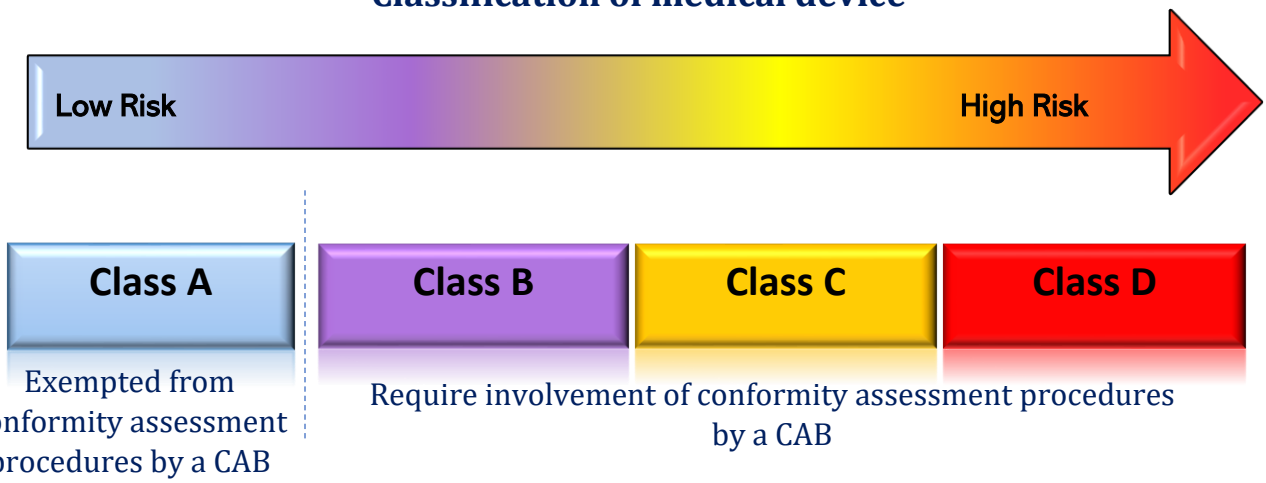
RULES OF CLASSIFICATION FOR GENERAL MEDICAL DEVICES

OVERVIEW

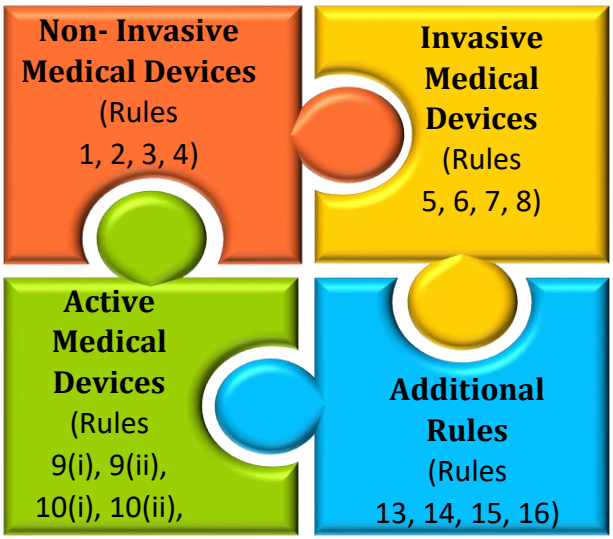
According to Section 3 of Medical Device Act 2012 (Act 737), Paragraph 3(1)(a) and First Schedule of Medical Device Regulation 2012, Medical Devices categorizes into 4 risk classes ranging from low to high risk: Class A, B, C, and D. The actual classification of each device depends on the claims made by the manufacturer and on its intended use.

The figure below illustrates the relationship between risk class, risk, and the requirement for involving a notified body:



CLASSIFICATION RULES

The classification for general medical device uses a rule-based classification system for medical devices. As per Appendix 1 of the Medical Device Regulation 2012, the Classification Rules are as follows:



Important Note: In the event of any dispute between an establishment and conformity assessment body over a classification of a medical device, the establishment may request in writing to the Authority within thirty days from the date of dispute to decide on the matter. Authority shall decide on the proper classification of the medical device concerned, whose decision shall be final.

For further information, refer Guidance Document on Rules of Classification for General Medical Devices

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