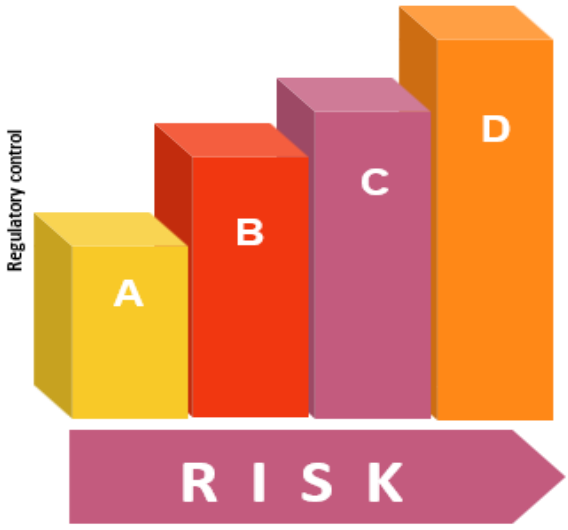
Rules of Classification for In Vitro Diagnostic Medical Devices

Classification of IVD medical devices is based on risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device.

It uses a set of classification rules based on:

- Intended use
- The technical / scientific / medical expertise of the intended user (lay person or healthcare professional)
- The importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician;
- The impact of the result (true or false) to the individual and / or to public health.

Conceptual illustration of regulatory requirements increasing with device risk class:



Prepared on 6th Feb 2024

Classification rules:

There are seven classification's rules of IVD medical device:

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.