Regulation stage

In vitro diagnostic guide

In vitro diagnostic

In vitro diagnostic (IVD) is a type of medical device, usually a reagent, calibrator, apparatus, equipment or system used in vitro to examine specimens such as blood, tissue and urine. Examples include:

- pregnancy tests
- blood glucose monitors
- HIV test kits
- certain blood collection tubes
- immunoassays

IVDs are regulated by Part IV of the UK MDR 2002 and all IVDs must be registered with the MHRA. There are four categories of IVDs, listed in order of perceived risk:

- general IVDs
- IVDs for self-testing which are intended to be used by persons in a home environment
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part Ill of Schedule 2A to the UK MDR 2002)
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List A (as modified by Part Ill of Schedule 2A to the UK MDR 2002)

General IVDs can be self-certified, but all other IVDs need approval from a UK approved body or EU notified body before they can be registered with the MHRA and placed on the UK market. Find out more about the IVD directive and what regulatory approval your IVD needs to go through.