Regulation stage

In vitro diagnostic medical devices guide

In vitro diagnostic medical devices

In vitro diagnostic (IVD) medical devices are usually a reagent, calibrator, apparatus, equipment or system used in vitro to examine specimens such as blood, tissue and urine for a clinical purpose. Examples include:

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

IVDs include specimen receptacles, and products specifically designed for use in IVD examination, but not products which are for general laboratory use.

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. This can include hormone tests and clinical chemistry tests
- IVDs for self-testing which are intended to be used by people in a home environment, excluding those that fall into the two categories below
- 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). This includes reagents for measuring blood sugar and products for rubella, toxoplasmosis and phenylketonuria
- 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). This includes reagents and products for HIV I and II, hepatitis B, C and D, and reagent products for determining ABO systems and anti-Kell, including those used to test donated blood, plus tests for screening

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. CE mark certification for IVDs is valid until 2030, after which a UKCA mark will be required.

Further guidance is provided by the MHRA.