

Regulation stage

In vitro diagnostic medical devices guide

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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 III 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 III 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.