

Possible Ways to Register IVD Analyzer

01 IVD Analyzer



Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures. These instruments are classified as class A, whereas reagents and kits are classified in their own right.

EXAMPLES (non-exhaustive)

- Enzyme immunoassay analyser, PCR thermocycler, microplate reader, clinical chemistry analyser.
- Instrument for automated purification of nucleic acids and automated nucleic acids extractor

Ref: MDCG 2020-16 rev.2

02 Analyzer in combination with the reagents, calibrators, controls, buffer/washing solutions



Follow class of reagent
For examples:

CLINICAL CHEMISTRY ANALYZER + Reagent assay + Diluent
IMMUNOASSAY ANALYZER-COAGULATION + D-Dimer reagent + D-Dimer control

Ref: MDA/GD/0001

03 Interdependent Analyzer – with condition as below



If the instrument has an independent measuring function which does not use any additional reagents, it is classified according to the intended purpose of the analysis (including instruments controls or instrument quality control).

Example: cell counting analyzers used in haematology, ion selective electrodes, instruments measuring blood gases or glucose via its sensors, specific gravity measurements in urine analysis, mass spectrophotometer for bacteria identification, erythrocyte sedimentation rate analyser etc.

Ref: MDCG 2020-16 rev.2

Remark: For any inquiry please email to ivd.registration@mda.gov.my

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