In vitro diagnostic (IVD) device classification flowchart

Based on Regulation (EU) 2017/746 on in vitro diagnostic medical devices

**Rule 1**
Does the IVD device detect the presence of or exposure to any of the following transmissible agents?
- Biological agents in blood, blood components, cells, tissues, or organs for transplant
- Biological agents that cause life-threatening disease with a high risk of propagation

Can the IVD device be used to determine the infectious load of a life-threatening pathogen when monitoring is critical for patient management?

*Example:* Tests used to measure SARS-CoV-2 viral load

**Rule 2**
Is the IVD device intended for analysis of any of the following markers?
- ABO system (A, B, AB)
- Rhesus system (Rh1, Rh2, Rh3, Rh4, Rh5, Rh6)
- Kidd system (K1, K2)
- Duffy system (FY1, FY2)

*Example:* Immunological tests used to assess the compatibility of transplant donors and recipients

**Rule 3**
Is the IVD device intended for any of the following applications?
- Detecting sexually transmitted agents
- Detecting infectious disease agents
- Genetic testing
- Cancer screening
- Prenatal screening
- Companion diagnostics
- Management of life-threatening diseases
- Congenital disease screening

*Example:* STI screening tests

**Rule 4**
Is the device intended for self-testing?
- Pregnancy testing
- Fertility testing
- Measuring cholesterol levels
- Detection of glucose, erythrocytes, leukocytes, or bacteria in urine

*Example:* Tests for the detection of glucose in serum, plasma, or urine

**Rule 5**
Does the IVD device fall into one of the following categories?
- General laboratory use
- IVD reagents without critical characteristics
- Instruments
- Specimen receptacles

*Example:* Products meant for laboratory use only

**Rule 6**
Is the IVD device not covered by any of the other classification rules?

**Rule 7**
Is the IVD device intended for any of the following self-testing applications?
- Blood, cells, tissues, or organs
- Biological agents in blood, blood components, cells, tissues, or organs
- Biological agents that cause life-threatening disease with a high risk of propagation

*Example:* Controls used to assess the performance of molecular assays for qualitative pathogen detection

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Class D

Class C

Class B

Class A