All devices will need to be divided into classes, A, B, C, or D, taking into account their purpose intended by the manufacturer and inherent risks. The Classification map below allows you to allocate your device correctly. Application of the classification rules shall be governed by the intended purpose, novelty, complexity and inherent risk of the devices.

IVDR Classification rules under the IVDR

Transmissible Disease: Blood or tissue compatibility
- Blood screening
- High risk disease
- High risk blood groups
- For full scope
- Click here

Infectious disease
- Cancer testing
- Companion diagnostics
- Genetic testing
- Congenital screening
- Self testing
- Self test: Exempted List
- All near-patient tests are classified in their own right

Specific IVD reagents
- Instruments
- Specimen receptacles
- None of the other rules
- Controls no assigned values

None of the other rules

For full scope
Click here