

CLASS
C

HIGH PERSONAL RISK,
MODERATE TO LOW PUBLIC
HEALTH RISK

Examples



- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests

CLASS
B

MODERATE TO LOW
PERSONAL RISK,
LOW PUBLIC HEALTH RISK

Examples



- Thyroid, kidney, liver function tests
- Infertility assays
- Clinical chemistry
- Hormones, enzymes, proteins
- Inflammatory markers
- Rheumatology markers
- Self-test devices that are not Class C: pregnancy, fertility, cholesterol and urine tests for glucose, erythrocytes, leucocytes and bacteria

CLASS
D

HIGH PUBLIC HEALTH RISK,
HIGH PERSONAL RISK

Examples



- HIV 1/2
- Hepatitis C virus
- Hepatitis B virus
- HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems
- CHAGAS
- Syphilis (used to screen blood donations)

CLASSIFICATION OF IVDS

- Re-classification of IVDs will mean 80-90% will no longer be able to 'self certify' conformity
- Review of technical documentation will be at the same depth for all devices, but there will be sampling proportionate to risk
- More scrutiny on risk, clinical evidence and post-market surveillance
- 'Near patient tests' are classified in their own right

CLASS
A

LOW PERSONAL RISK,
LOW PUBLIC HEALTH RISK

Examples



- Accessories
- Wash buffers
- Specimen receptacles
- Instruments
- Culture media