

# 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 (screening and diagnosis)
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests
- Cardiac markers
- Tissue typing e.g. HLA



MODERATE TO LOW PERSONAL RISK,  
LOW PUBLIC HEALTH RISK

# CLASS B

## 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



- Blood donation screening e.g. Syphilis, CHAGAS, HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems.
- Diagnostic test e.g. HIV 1/2

## 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

LOW PERSONAL RISK,  
LOW PUBLIC HEALTH RISK

# CLASS A

## Examples



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