CLASS

HIGH PERSONAL RISK, MODERATE TO LOW PUBLIC **HEALTH RISK**

Examples



CLASS

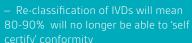
- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers (screening and diagnosis)
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests
- Cardiac markers
- Tissue typing e.g. HLA



CLASSIFICATION OF IVDS

- 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
- 'Near patient tests' are classified in





MODERATE TO LOW PERSONAL RISK, LOW PUBLIC HEALTH RISK

CLASS

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

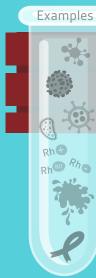


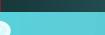
LOW PERSONAL RISK, LOW PUBLIC HEALTH RISK



Examples







· Blood donation screening e.g. Syphilis, CHAGAS, HTLV I/II

HIGH PUBLIC HEALTH RISK,

HIGH PERSONAL RISK

• Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems.

• Diagnostic test e.g. HIV 1/2