Regulation of Remote Diagnostics in the UK

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The outlook for UK IVD regulation

A robust, world-leading regulatory system for medical devices in UK that prioritises patient safety.

Why change the status quo?

1. More patient and public **safety, access and choice**
2. A more **attractive market** for medical devices – viable, easier and faster to bring products to market safely
3. International **best** practices
4. Global **leader** in regulation
5. To adapt more readily to **technological change**

The MHRA - Looking to the future

We aim to deliver a UK healthcare environment that is globally attractive to developers and manufacturers of medical products to benefit patients and the healthcare service

1

Patients First

- ✓ Putting patients first and becoming a world leading regulator to protect public health through excellence in regulation and science

2

Collaboration

- ✓ Collaboration with other bodies in the UK including the maximisation of regulatory collaboration with NICE and NHS

3

Health system

- ✓ Continue to play pivotal role in the health and social care system

4

International relationships

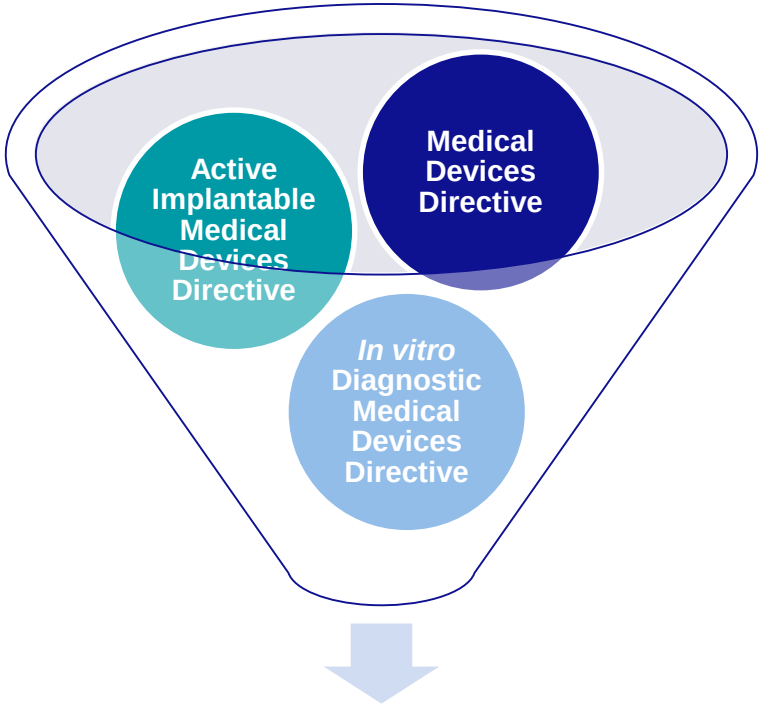
- ✓ Commitment to excellent international relationships to deliver high standards of patient protection and support access to innovative products

UK Legislation

- Diagnostics are regulated in the UK under the **UK Medical Devices Regulations 2002** (UK MDR 2002)

- The UK MDR 2002 is based on existing EU legislation which has been transposed into UK law

- **The Medicines and Medical Devices Act (2021)**:
  - allows us to update the UK MDR 2002
  - consolidates enforcement provisions
  - provides for a device information system
  - allows for enhanced data sharing



Standstill Position

Great Britain

- EU IVDR not implemented
- Recognition of CE marking until 30 June 2023
- UKCA marking required after 30 June 2023
- Approved Bodies can now conduct assessments for the UKCA mark

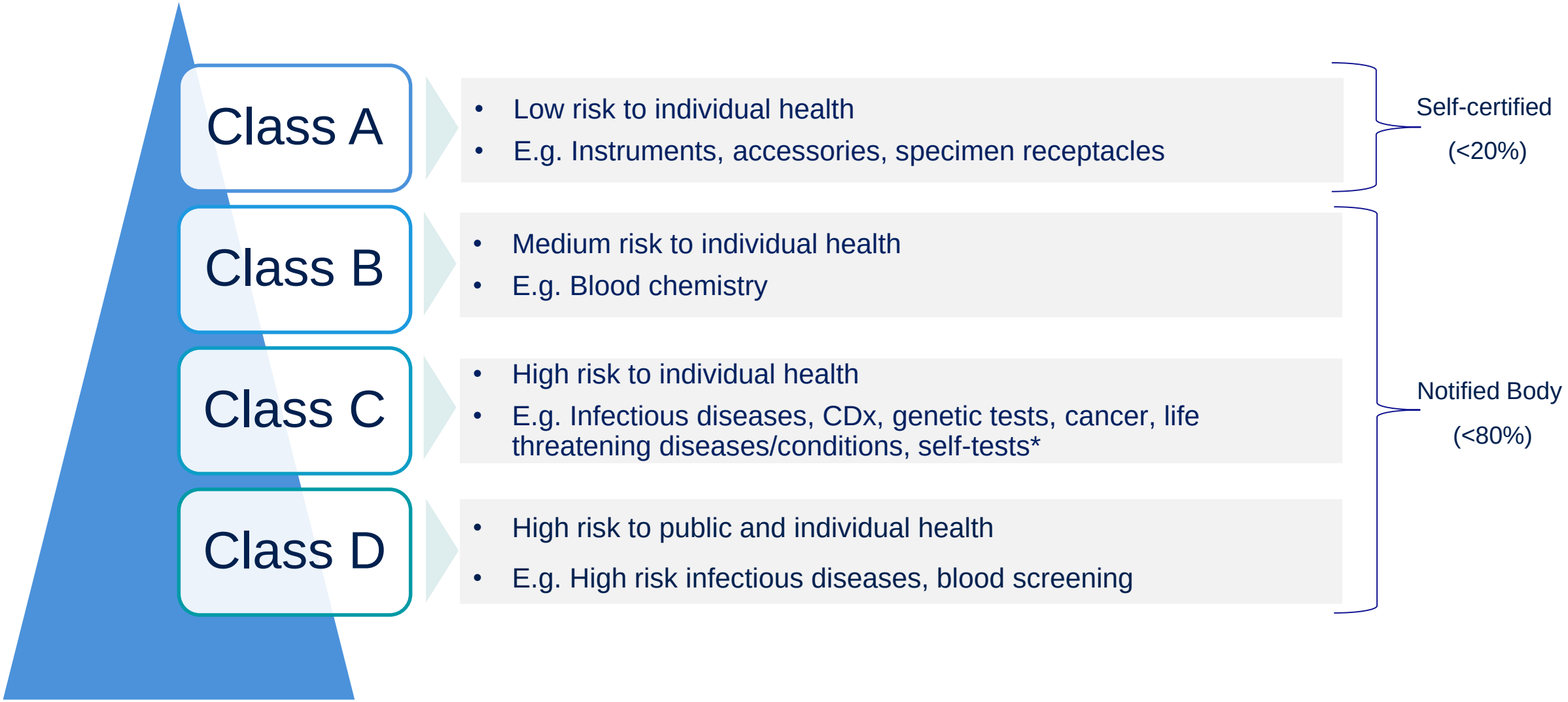
Northern Ireland

- EU IVDR implemented 26th May 2022.
- Revised transition timescales apply – but no delay!
- Devices must be CE or CE UKNI marked
- CE UKNI applied where UK Notified Body used for conformity assessment

EU IVDR: Key changes

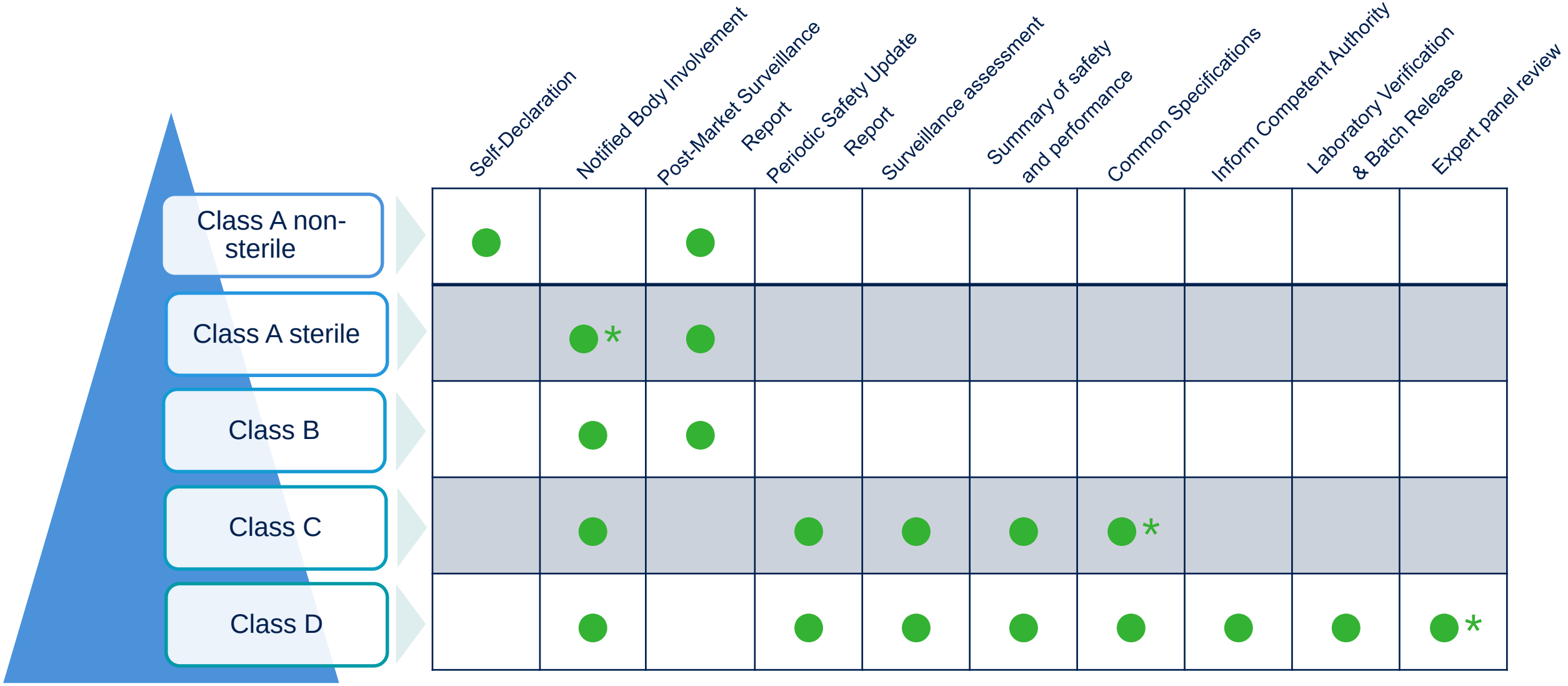
1	**Device Classification**	*Overhaul of IVD classification principles to a risk-based, rather than a list-based, approach*
2	**Performance evaluation studies**	*New scrutiny placed on IVD studies & PE updated throughout lifecycle improving the safety of devices placed on the market*
3	**Increased pre-market requirements**	*Increased requirements for pre-market data especially in the highest risk IVDs. Providing assurance of safer and better performing tests*
4	**Increased post-market requirements**	*Legislative requirements for post market follow up, risk management and reporting, increased oversight of long term data and trends.*
5	**Notified Bodies**	*New regulations set out enhanced requirements for Notified Bodies*

EU IVD-R : Device Classification



**excluding for pregnancy; fertility; cholesterol; and urine glucose, erythrocytes, leucocytes and bacteria*

EU IVDR : Impact of Classification



IVDR key changes for remote diagnostics

- *Classification*
  - *Devices for self testing** - regulated as Class C
  - *Devices used for testing services offered to lay persons by means of information society services* - included within the updated definition of devices for self testing .
  - *Devices for Near-Patient testing* - defined and classified in their own right
  - *IVD Software* - defined and classified depending on its use.
- *Enhanced GSPRs for self-testing and near-patient testing, including for design, manufacture and labelling.*
- *Enhanced requirements for conformity assessment for self-testing and near-patient testing by Notified Bodies.*
- *Specific requirements for Performance Evaluation and Performance Studies*

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Future Opportunities in GB

International alignment and alternative routes to UK market

- Medical Device Single Audit Programme (MDSAP), Single Review (MDSRP) and Domestic Assurance

Pathways for innovative MedTech

- Smooth passage to market for innovative devices.

Risk proportionate regulation of IVDs

- genetic tests, companion diagnostics, direct to consumer tests

Performance Evaluation -scientific, analytical and clinical

- Expand research infrastructure to support industry (e.g. UKHSA, UKRI, NIHR)

Post-Market Surveillance

- Use of real-world data including IVD registries and EQA to support PMPF and PMS

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