



Medicines & Healthcare products
Regulatory Agency

Regulatory standards

What benchmarks need to be met for IVDs?

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Medicines &
Healthcare products
Regulatory Agency

We are the UK regulator of medicines, medical devices and blood components for transfusion. We are responsible for making sure these products meet set standards for safety, quality and efficacy.

The MHRA is an Executive Agency of the Department of Health and Social Care.



MHRA



**British
Pharmacopoeia**



**UK Stem
Cell Bank**



Yellow Card



NIBSC



CPRD



What are
the standards
?

the standards

**S**

Safety

Essential Requirements: General Requirements

- Design and manufacture that will not compromise the clinical condition or safety of the patients, users, other persons or property
- Risks are weighted against benefits
- High levels of protection of health and safety
- Conforms to safety principles, considering generally acknowledged state-of-the-art

**E**

Efficacy

Essential Requirements: General Requirements

- Analytical sensitivity & specificity
- Clinical (diagnostic) sensitivity & specificity
- Accuracy, repeatability, reproducibility
- Control of relevant interferences
- Limits of detection

**Q**

Quality

Essential Requirements: Design and Manufacturing Requirements

- Chemical, physical and biological properties, incl. infection and microbial contaminations
- Manufacturing and environmental properties
- Protection against radiation, mechanical and thermal risks
- Specific requirements for devices for self-testing
- Packaging & labelling including instructions for use

In the regulation



STATUTORY INSTRUMENTS

2002 No. 618

CONSUMER PROTECTION

The Medical Devices Regulations 2002

Made	20th May 2002
Laid before Parliament	21st May 2002
Coming into force	13th June 2002

The IVD regulations transposes the IVD Directive clauses.

The IVD Directive was in place across the EU until 2017 and was replaced by EU IVDR (2017/746) that came into effect since May 2022.

The UK exited the EU in 2019 and before the coming into effect date of the IVDR and therefore IVDR **does not apply in Great Britain**.

<https://www.legislation.gov.uk/ukSI/2002/618/introduction>

PART IV In Vitro Diagnostic Medical Devices

32. Interpretation of Part IV

33. Scope of Part IV

33A. Registration etc. of persons placing in vitro diagnostic medical devices on the market

34. Essential requirements for in vitro diagnostic medical devices

34A. Approval requirement for coronavirus test devices

34B. Public sector use of coronavirus test devices

34C. Transitional provisions for coronavirus test devices

34D. Exemption for coronavirus test devices in conformity with Regulation (EU) 2017/746 and Regulation (EU) 2022/1107

35. Determining compliance of in vitro diagnostic medical devices with relevant essential requirements

36. UK marking of in vitro diagnostic medical devices

36A. UK(NI) indication: in vitro diagnostic medical devices

37. UK marking of in vitro diagnostic devices that come within the scope of this Part and other legislation

38. In vitro diagnostic medical devices not ready for use

38A. Applications for approval of coronavirus test devices

38B. Performance requirements for coronavirus test devices

38C. Register of approved coronavirus test devices

39. Exemptions from this Part

39A. Exemptions for coronavirus test devices

40. Procedures for affixing a UK marking to in vitro diagnostic medical devices

41. Manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices

42. Approved bodies and the conformity assessment procedures for in vitro diagnostic medical devices

43. Devices for performance evaluation

44. Registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation

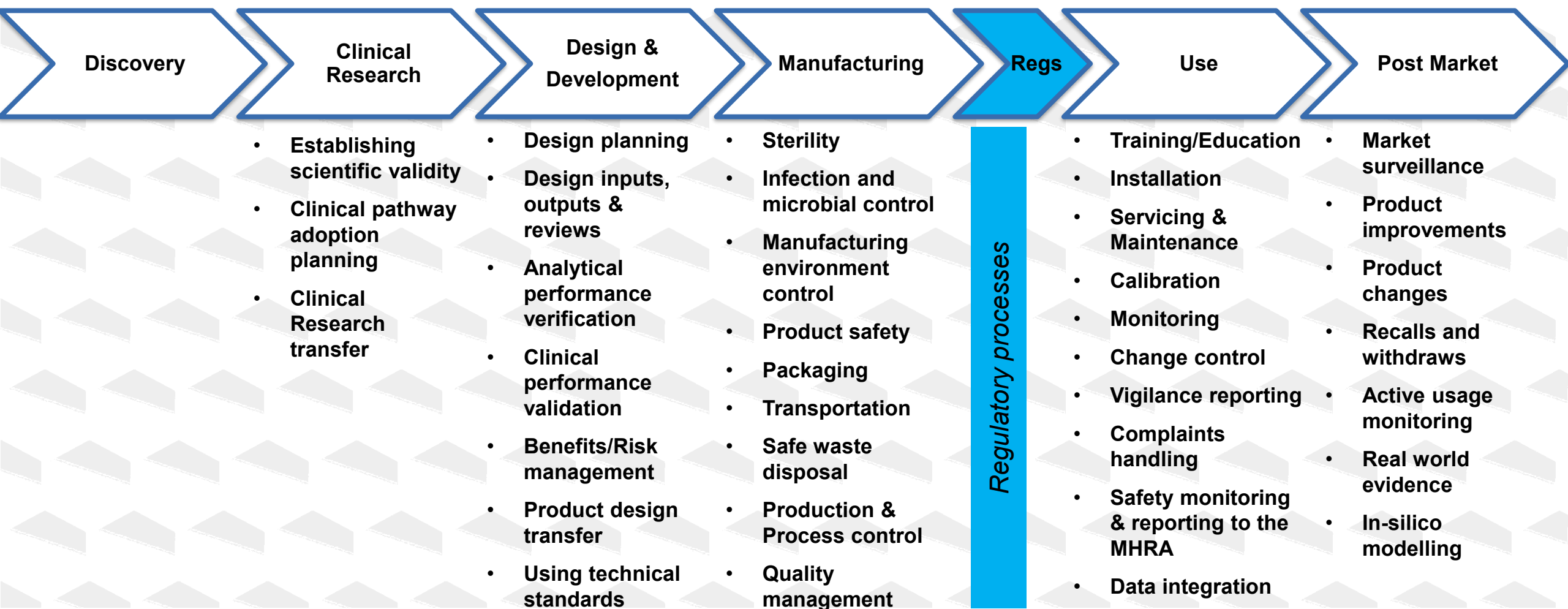
44ZA. Obligations in Part IV which are met by complying with obligations in Directive 98/79

44ZB. Obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746

When are the standards to be applied?



When are the standards to be applied?



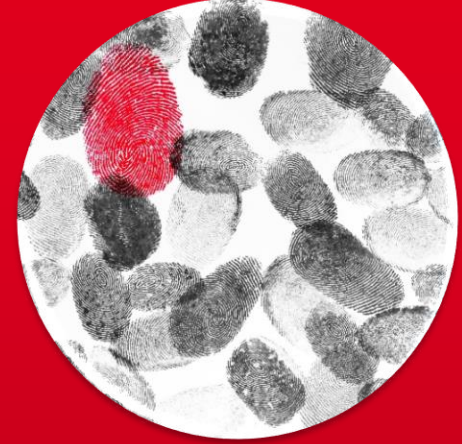
Expected Outcomes



**Well-defined
Intended Use**



**Established
Clinical
Evidence**

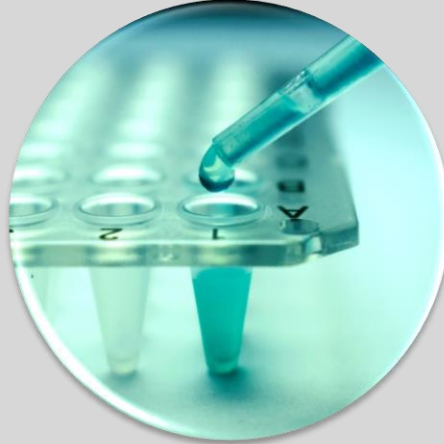


**Reliable
Results Data**

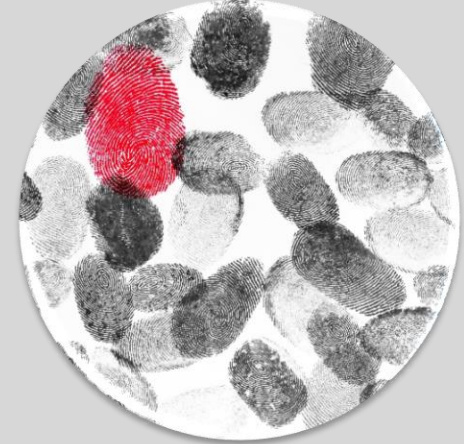
Expected Outcomes



- The objective intent of the IVD
- A general description of the disease or condition
- Identify users and environment
- Safe usage practices
- Test procedure described
- Precautions and warnings given
- Results interpretation

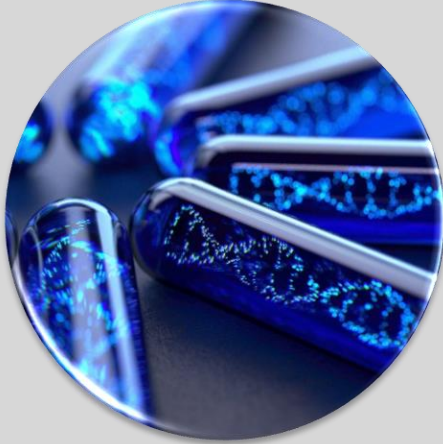


**Established
Clinical
Evidence**

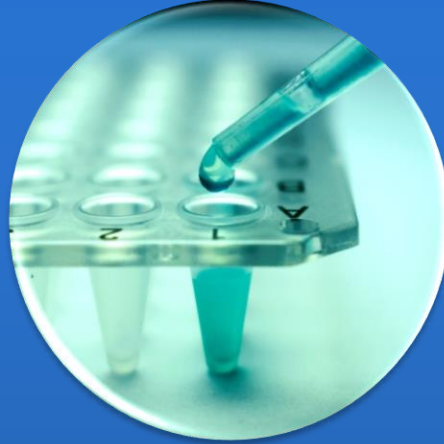


**Reliable
Results Data**

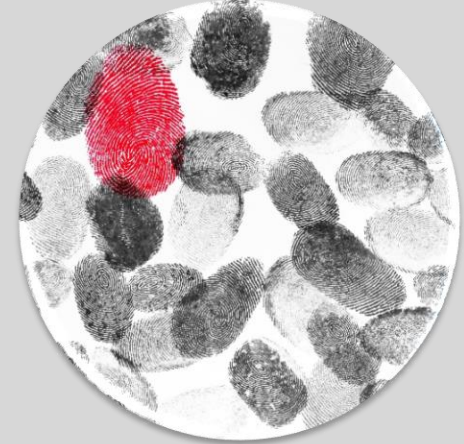
Expected Outcomes



**Well-defined
Intended Use**

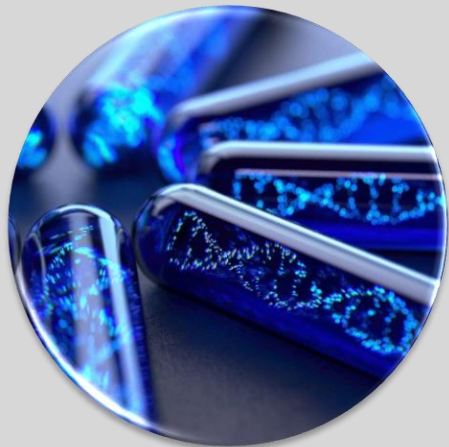


- Analytical performance / verification testing
- Clinical performance / validation testing
- Human factors testing
- Use valid statistical techniques
- Adopt Technical Standards
- Claims based on scientific data

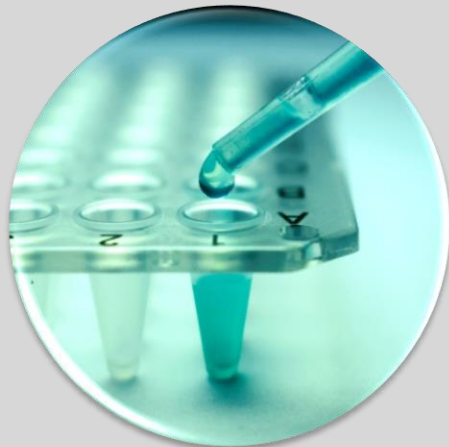


**Reliable
Results Data**

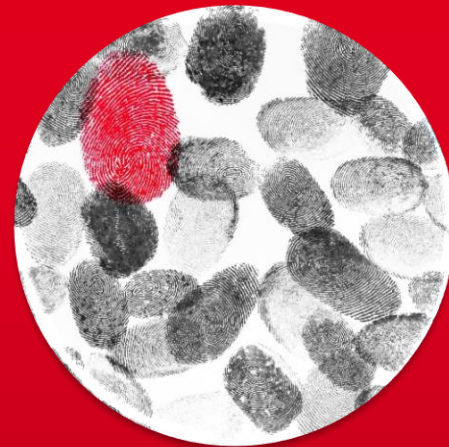
Expected Outcomes



**Well-defined
Intended Use**



**Established
Clinical
Evidence**



- Clinical validity to accurately and reliably detect/predict a clinical condition or disease for the target patient population
- Demonstrates accuracy (incl. Trueness, Repeatability & Reproducibility) of measurement methods and test results
- Test is fit for the intended purpose

Regulators are your best friends too

- We are normal human beings.
- We apply the applicable legislations, technical standards and guidance.
- Regulations are simply the standards for Safety, Quality and Efficacy

So...

- 1. Learn and apply the regulations**
- 2. Seek help to understand the meanings of each regulation**
- 3. Inform us when something isn't working**



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