Hardian Health

Innovate UK

Health Innovation Network South London

# Module 1: Meet the Regulators

Overview of who is responsible for medical device regulation in the UK and EU and their regulatory legislative infrastructures.

# Outline

This module will cover:

- What are regulations?
  - The purpose of regulations
  - Introduction to medical device regulation
- Who are the regulators?
  - Medical device regulation in the UK and the EU
- Multiple choice questions

# Purpose of regulation

Medical Device Regulations**: Safe, Effective and Cybersecure**

Many complex systems in society are regulated, including medical devices.

The main aim of regulation is to protect patients, by ensuring the safety, effectiveness and cybersecurity of any medical devices placed on the market.

Regulators often act within a framework of other bodies to maintain and enforce the regulations relevant to that jurisdiction.

# Regulatory infrastructure

| | Medical device patient safety | Data protection cybersecurity |
|---|---|---|
| UK | • Medicines and Medical Devices Act 2021<br>• UK Medical Device Regulation 2002 (SI 2002 No. 618, as amended by Brexit) | • Data Protection Act 2018<br>• UK GDPR ⇔ EU GDPR |
| EU | • EU 2017/745 Medical Device Regulation (MDR) | • EU 2016/679 General Data Protection Regulation (GDPR)<br>• EU AI Act (adopted May 2024) |

# UK regulatory infrastructure

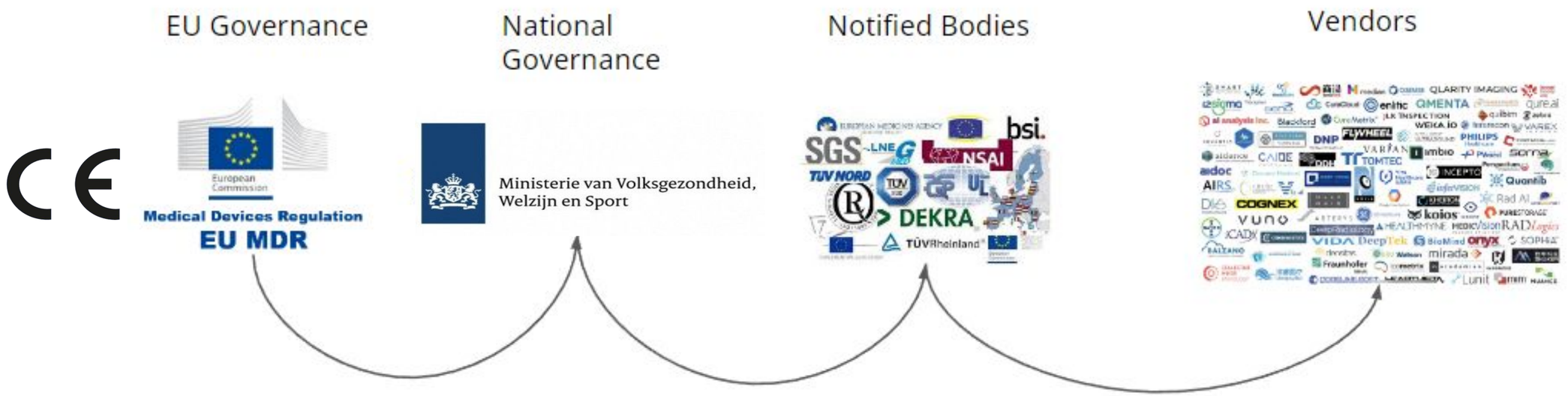
UKCA

National Governance

Approved Bodies

Vendors

# EU regulatory infrastructure



# Summary

Medical device regulations are in place to protect patients by ensuring the safety, effectiveness and cybersecurity of medical devices on the market.

The MHRA is responsible for overseeing and enforcing the medical device regulations in the UK. They select Approved Bodies to carry our conformity assessments and issue UKCA mark certificates.

Each EU member state has a competent authority enforcing the EU MDR. In the EU, Notified Bodies perform conformity assessments and issue CE mark certificates.

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