



UNITED KINGDOM MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the UK market

1 Confirm the UK regulatory identity

Confirm intended purpose, target users, technology, and device type. Determine whether the product is software/AI, active, implantable, sterile, measuring, or reusable surgical.



GREAT BRITAIN vs. NORTHERN IRELAND:

Great Britain (England, Scotland, Wales) uses UKCA.
Northern Ireland follows EU rules with CE / CE UKNI.



General medical device



Sterile / measuring / reusable



Software / active / implantable

2 Choose the UK market-entry route

CLASS I



Lowest risk

- Most Class I devices can be self-declared by the manufacturer.
- Class I sterile, measuring, and reusable surgical instruments require Approved Body involvement for those aspects.

CLASS IIa



Low-to-moderate risk

- Requires Approved Body involvement.
- Further third-party assessment proportionate to risk.

CLASS IIb



Moderate-to-high risk

- Requires Approved Body involvement.
- Greater third-party assessment and evidentiary review.

CLASS III



Highest risk

- Requires Approved Body involvement.
- Most rigorous assessment and evidence expectations.



Classification is determined under the UK MDR 2002 (as amended). Higher classes face greater evidence, clinical evaluation, and quality system expectations.

3 Build the UK market-access infrastructure



MHRA / UK MDR 2002 framework

Medical Devices Regulations 2002 (as amended) implement the UK's regime. Follow MHRA guidance and UK legislation.



UK Responsible Person (for non-UK manufacturers)

Non-UK manufacturers must appoint a UK Responsible Person to place devices on the Great Britain market.



Device registration with MHRA

Register devices (and systems) on the MHRA database prior to placing on the Great Britain market.



Conformity marking strategy

UKCA for Great Britain.
CE / CE UKNI for Northern Ireland.

- CE-marked MDR devices accepted on Great Britain market until 30 June 2030.
- EU MDD/AIMDD general devices accepted until the sooner of certificate expiry or 30 June 2028.

4 Build the evidence stack



Administrative

Device description, intended use, variants, indications, regulatory history, and market claims.



Quality / QMS

QMS aligned with UK MDR 2002 requirements. ISO 13485 and supplier control.



Verification & validation

Design verification and validation, including software, cybersecurity, and performance testing.



Clinical / usability / cyber

Clinical evaluation and PMS plan. Usability engineering and cybersecurity per applicable standards.



Labeling / registration

Labeling, IFU, UDI, language requirements, symbols, and MHRA registration records.



RA TRAP TO AVOID

Don't confuse Great Britain and Northern Ireland rules or assume UKCA alone works in Northern Ireland. Incorrect marking or representative strategy can block market access and lead to non-compliance.



STRATEGIC INSIGHT

Choose early whether the launch path is Great Britain-first, Northern Ireland/EU-aligned, or dual-market. The choice impacts marking, representative, labeling, registration, and evidence strategy.



UNITED KINGDOM MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch

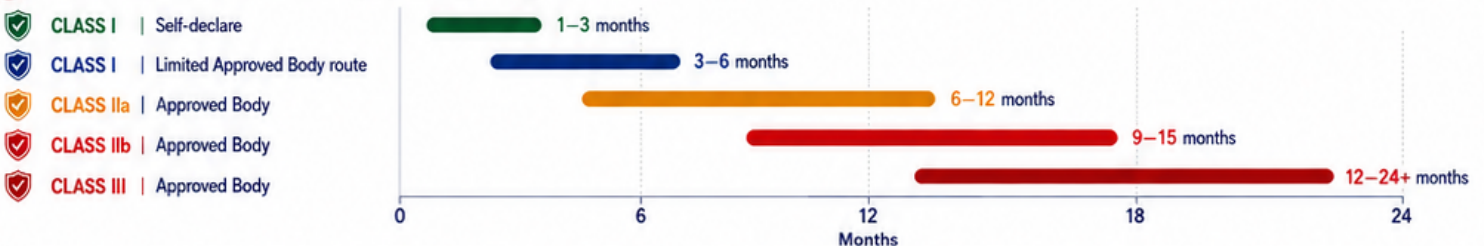
A Program flow



B What gets heavier as risk and novelty rise?

Signal	CLASS I	CLASS Is/Im/Ir	CLASS IIa	CLASS IIb	CLASS III
Pathway intensity	Very low ● ● ● ● ●	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Basic-moderate ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical support	Not usually required ● ● ● ● ●	Limited ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Extensive ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Basic-moderate ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Lower-moderate ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges



Great Britain (UKCA) and Northern Ireland (CE) routes differ. Choose the route that matches where the device will be placed on the market.



Timelines are planning ranges only; actual duration depends on device complexity, clinical evidence needs, novelty, supply chain, and regulator/Approved Body capacity.

D Labeling & language essentials

English-language labeling / IFU
All labeling and IFU must be in English, clear, accurate, and validated.

UK Responsible Person (UKRP) details
Name and address of UKRP required where applicable and must be kept up to date.

Claims control
Claims must be truthful, verifiable, and supported by evidence for the intended audience.

Software / cybersecurity considerations
Address cybersecurity, software lifecycle, and risk controls appropriately.

Registration / listing readiness
Ensure device details, UDI, and certificates match submissions exactly.

Vigilance / post-market reporting
Establish PMS, trend monitoring, and PSUR/PMCF expectations.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- MHRA — Regulating medical devices in the UK
- MHRA — Device registration guidance
- Medical Devices Conformity Assessment and the UKCA mark
- Northern Ireland devices guidance
- Approved bodies and conformity assessment guidance



IMPORTANT

Product-specific requirements, current transitional policy, classification, and route selection govern. Confirm before execution.