UK MHRA Guidelines - Post-Brexit Regulations

After Brexit, the UK established an **independent MHRA regulatory system** and introduced **UKCA marking**

GB UKCA Marking

Conformity marking exclusively for UK (GB) market

Transition Period

CE marking recognized with limitations (deadline may be extended)

MHRA Regulatory Requirements

- **Registration:** Manufacturer and device registration with MHRA required
- **UK Responsible Person:** Designation of legal representative in the UK
- **Approved Body:** Review organization equivalent to EU's Notified Body
- **Northern Ireland:** CE marking can continue to be used

GB (England, Wales, Scotland)

UKCA marking required

Northern Ireland

Uses CE marking

Dual Marking

Required for simultaneous entry into EU+UK markets

💡 **Key Point:** If planning to enter both EU and UK markets, you must comply with both regulatory systems and undergo separate conformity assessments