UKCA update

2025-01

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Add value.
Inspire trust.

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Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge as subject matter experts.

This presentation presents personal understanding of the medical device requirements in Europe and might not reflect the view of all Notified Bodies!

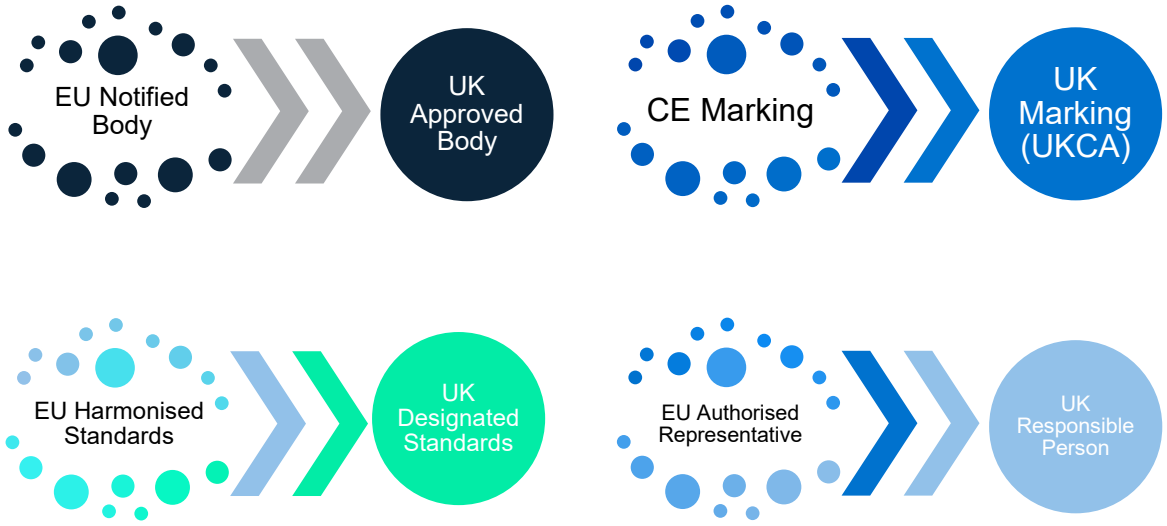
UK Medical Devices Regulations
Current requirements

The Medical Devices Regulations 2002
(SI 2002 No 618, as amended)(UK MDR 2002)

Current legislation

Amended by EU Exit Legislation Schedule 2A

Great Britain UKCA	Part II: general medical devices	MDD 93/42/EEC
	Part III: active implantable medical devices	AIMDD 90/385/EEC
	Part IV: in-vitro diagnostic medical devices	IVDD 98/79/EC
Northern Ireland	EU MDR & IVDR apply	



TÜV SÜD BABT Approved Body for Medical Devices

Status

UKAS Accreditation

- Accredited to ISO 17021-1 for delivery of ISO 13485 conformity assessment
- Full scope accreditation
- TUV SUD BABT UKAS Accreditation Scope

UK MDR 2002 Part II: General Medical Devices

- Designated for Part II of UK MDR 2002
- General Medical Devices - Non active medical devices and active, non-implantable medical devices
- TUV SUD BABT Medical Device Designation Scope

UK MDR 2002 Part III: Active Implantable Medical Devices

- Designated for Part III of UK MDR 2002 in progress
- Active Implantable Medical Devices
- TUV SUD BABT Active Implantable Medical Device Designation Scope

UK MDR 2002 Part IV: In-vitro Diagnostic Medical Devices

- Designation application for Part IV UK MDR 2002 (IVD) in progress
- IVD designation anticipated in 2025

What are the current legislative requirements for medical devices in UK?

The Medical Devices Regulations 2002 (SI 2002 No 618, as amended)(UK MDR 2002)

The Medical Devices (Amendment) (Great Britain) Regulations 2023

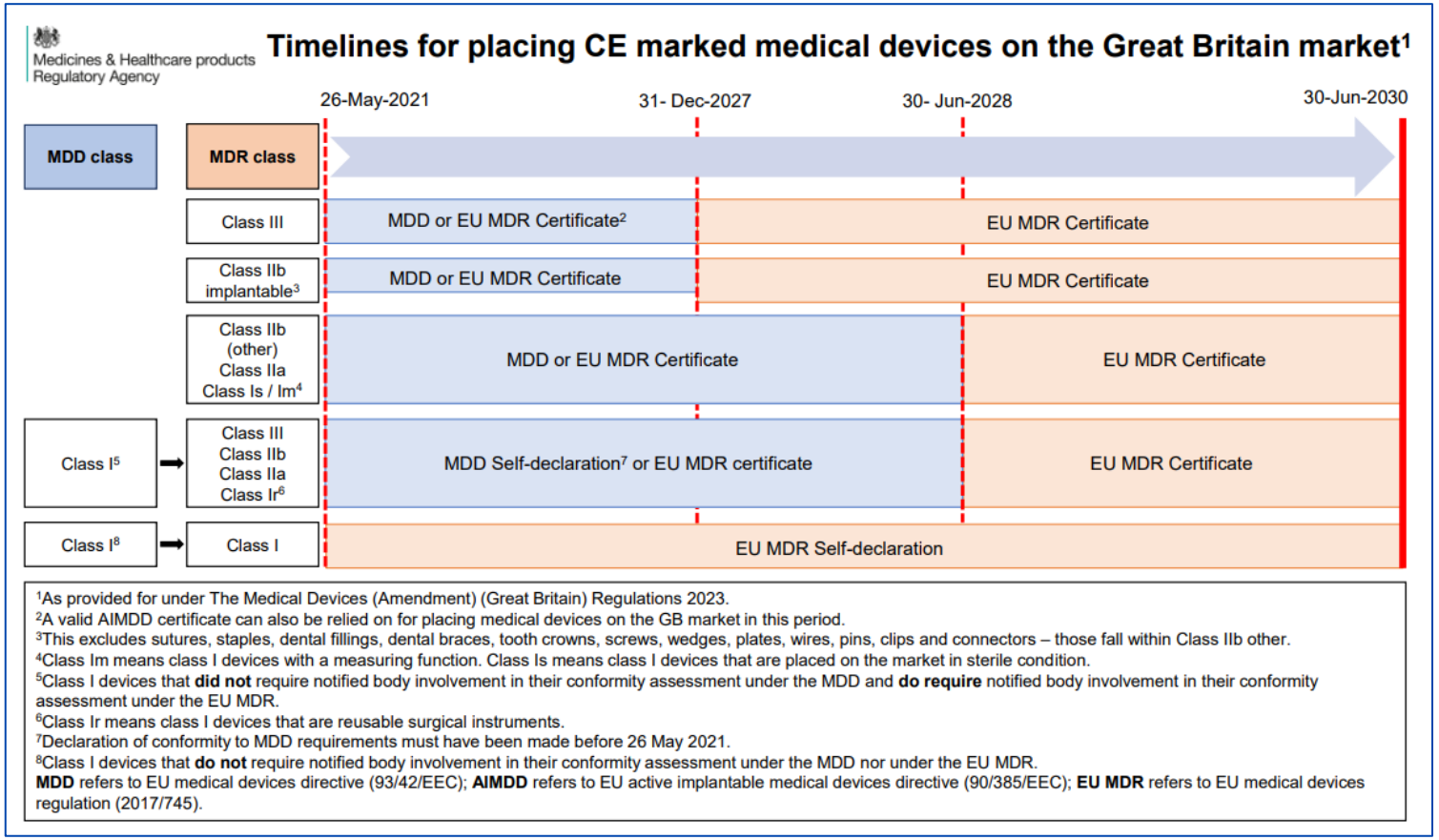
The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024

MHRA Medical Devices Regulatory Reform Roadmap.pdf

CE transition timelines

UK introduced legislation defining CE transition periods:
The Medical Devices (Amendment) (Great Britain) Regulations 2023 (legislation.gov.uk)

MHRA published infographic describing transition periods:
MHRA Infographic: transition periods under new UK SI



Medical Devices - PMS Requirements (GB) - Amendment 2024 Link

In force: **16 June 2025**

Applicable to medical devices placed on GB market under:	EU Directives (MDD, AIMDD, IVDD) CE
	EU Regulations (EU MDR, EU IVDR) CE
	UK MDR 2002 UKCA
Introduces new requirements:	Amended timelines for incident reporting and FSCA / FSN reporting
	Periodic safety update report (PSUR) for each device placed on market or put into service
	PSUR must include UK specific information / requirements
	PSUR submission / assessment by an Approved Body (where manufacturer contracted with an Approved Body)

PSUR submission frequencies:

- Class III/AIMD: Every year
- IIb i: Every Year
- IIa/IIb: Every 2 years
- Non Self declared IVDs: Every Year

Further guidance expected

Medicines & Healthcare products Regulatory Agency

Medical Devices Regulatory Reform

Roadmap to implementation

Version 2.0 (December 2024)

What is new?

Regulatory Reform Update, etc

GOV.UK

Home > Government > Brexit > Implementation of medical devices future regime

Medicines & Healthcare products Regulatory Agency

Standard

Statement of policy intent: international recognition of medical devices

Updated 11 December 2024

Contents
1. Purpose of this statement
2. Background
3. Our intended approach
4. Proposed access routes
5. Qualifying Northern Ireland goods
6. Ongoing activities
7. Enquiries

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1. Purpose of this statement

This statement describes the draft policy for recognition by the UK of international regulators' approvals of medical devices.

This statement and proposed framework applies to medical devices in Great Britain. For guidance on the regulation of devices in Northern Ireland, see Regulation of devices in Northern Ireland.

2. Background

The Government response to the 2021 consultation on the future regulation of medical devices in the United Kingdom detailed the intention to proceed with introducing alternative routes to market, which utilises approvals from other countries and Medical Device Single Audit Program (MDSAP) certificates, in addition to the current UKCA (UK

GOV.UK

Home > Health and social care > Medicines, medical devices > Medical devices regulation and safety > The Innovative Devices Access Pathway (IDAP)

Medicines & Healthcare products Regulatory Agency

Guidance

The Innovative Devices Access Pathway (IDAP) - pilot phase

Updated 29 February 2024

Contents
- Overview
- Partners
- The benefits the IDAP delivers
- The eight selected innovative medical devices
- Eligibility
- Eligibility criteria used in the IDAP pilot
- IDAP governance and patient and public involvement
- Further information

Print this page

The pilot phase of the development of a new pathway supporting innovative technologies to address unmet clinical needs in the UK has entered the next phase. The IDAP Partners have selected eight technologies that will receive tailored regulatory and access support.

Overview

The Innovative Devices Access Pathway (IDAP) pilot is an initiative to bring new medical technologies to the National Health Service (NHS) to help with medical needs that are currently unmet.

The aim of IDAP is to enable and improve patient access to innovative and transformative medical devices, by providing an integrated and enhanced regulatory

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Home > Business and industry > Science and innovation > Artificial intelligence

Press release

MHRA trials five innovative AI technologies as part of pilot scheme to change regulatory approach

The pilot scheme, AI Airlock, is designed to help test and improve the rules for AI-powered medical devices to ensure they reach patients quickly, safely and effectively.

From: Medicines and Healthcare products Regulatory Agency

Published 4 December 2024

Medicines and Healthcare products Regulatory Agency
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Read the latest on the MHRA's regulatory changes for medical devices

We've published the latest blog from Laura Squire OBE, our Med Tech Regulatory Reform Lead, where she shares an update on our programme of regulatory changes for medical devices.

The blog contains all you need to know about our intentions for the Post Market Surveillance regulation, a future Pre Market regulation, international reliance, MHRA team changes and more 👉 https://bit.ly/3zxqCTO

Regulatory reform update:
Plans for Pre-Market SI

- Increase some medical device classifications
- Introducte UDI requirements
- Introduce implant cards
- Introduce rules regarding claims made about medical devices in public

MHRA Consultation
Medical Devices Regulations: Routes to market & IVDs

Medicines & Healthcare products Regulatory Agency

Medical Devices Regulations: Routes to market and *in vitro* diagnostic devices

Consultation

Published 14 November 2024

Consultation closed 5 January 2025

International Reliance

- Intent to protect supply of medical devices to patients
- In line with routes in place for medicines since Jan 2024
- Statement of policy intent: international recognition of medical devices - GOV.UK

UKCA Marking

- Proposal for removal of requirement for physical UKCA marking
- Conformity assessment process unchanged

In vitro diagnostic devices

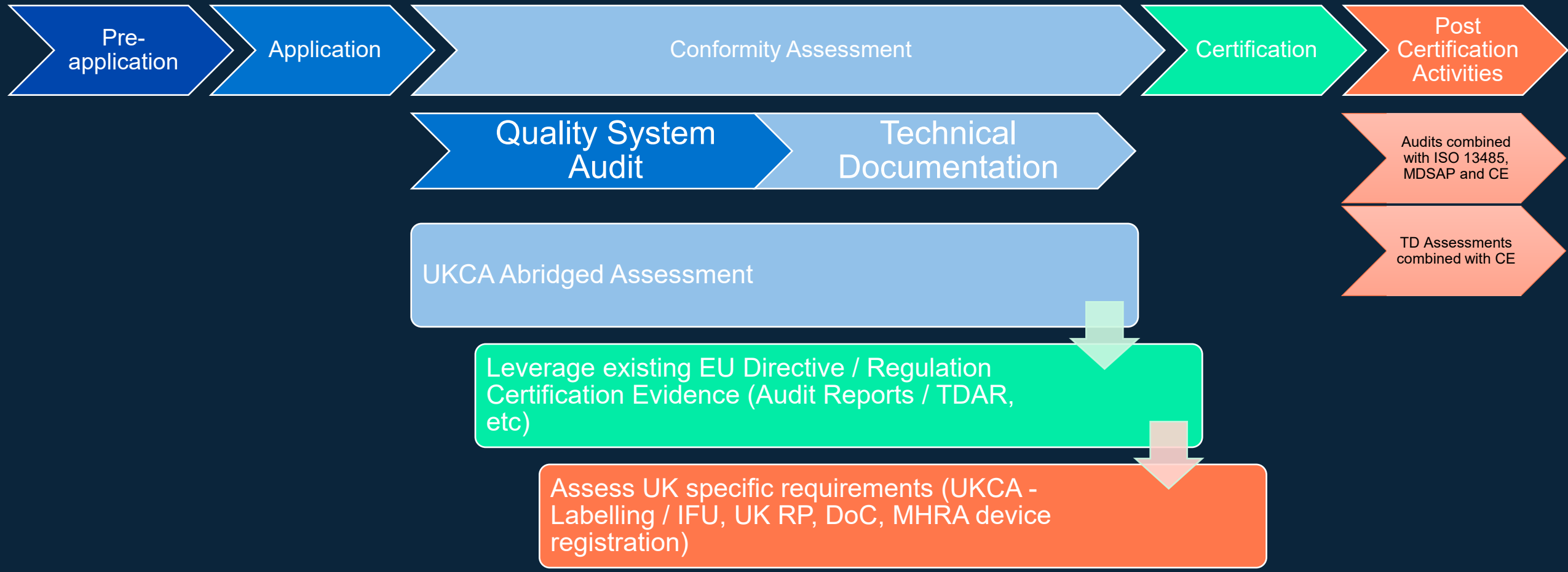
- Alignment with IMDRF IVD Classification rules (Principles of In Vitro Diagnostic (IVD) Medical Devices Classification)
- Class B IVD – Manufacturer self declaration and requirement for ISO 13485 QMS certification

Assimilated EU Law

- Proposal to delay expiry ('sunsetting date') of specific laws until such time as they are no longer needed
- Regulation (EU) No 920/2013 (designation of ABs); Regulation (EU) No 722/2012 (animal tissues); Commision Decision 2002/364 (IVD Common Specs); Commission Regulation (EU) No 207/2012 (eIFUs)

UKCA Abridged Assessment

Can we leverage existing EU CE evidence?



What does the service model look like?

1

UKCA only application
Full assessment to UKMDR
(EU MDD/IVDD/AIMDD)

TD assessment ↔ UKMDR assessment
QMS assessment ↔ UKMDR assessment

→ UKCA 0168

2

Initial combined application
UKMDR + EU MDR

TD assessment (EU MDR) → UKMDR abridged assessment
QMS assessment (EU MDR) → UKMDR abridged assessment

→ CE 0123
→ UKCA 0168

3

Also applicable to manufacturers with valid CE certification from another EU NB

Initial application with existing CE
UKMDR + EU MDR
or
UKMDR + EU MDD/AIMDD

* CE verification review
UKMDR abridged assessment

→ UKCA 0168

* Depending on the evidence provided, TÜV SÜD may be required to conduct further assessment (e.g. further documentary evidence, additional audit/TD assessment)

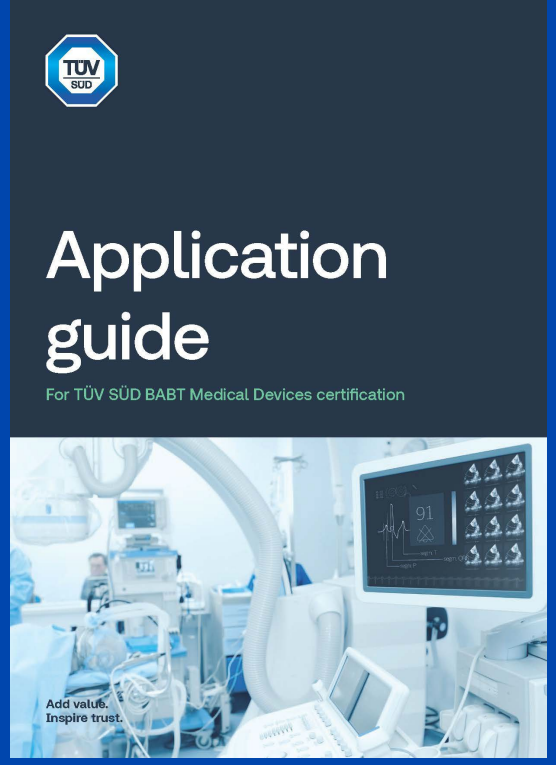
Some documentation required for Abridged Assessment

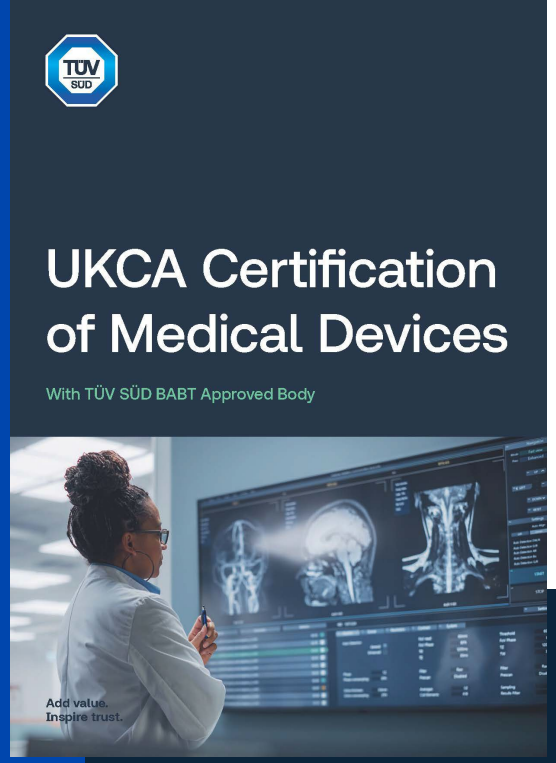
- Registration of devices with MHRA
- Appointment of UK Responsible Person (if manufacturer outside UK)
- Labelling - UKCA mark (labels & IFU)
- UKMDR Essential Requirements checklist
- Incident reporting to MHRA
- Declaration of Conformity to UKMDR (draft)

Thank you

Website

- UKCA for Medical Devices | TÜV SÜD (tuvsud.com)
- TUV SUD BABT Medical Devices Application Guide





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