BSI update on the new UKCA for medical devices and IVDs

Routes to market for NI and GB, labelling principles and BSI UKCA Conformity Assessment Model

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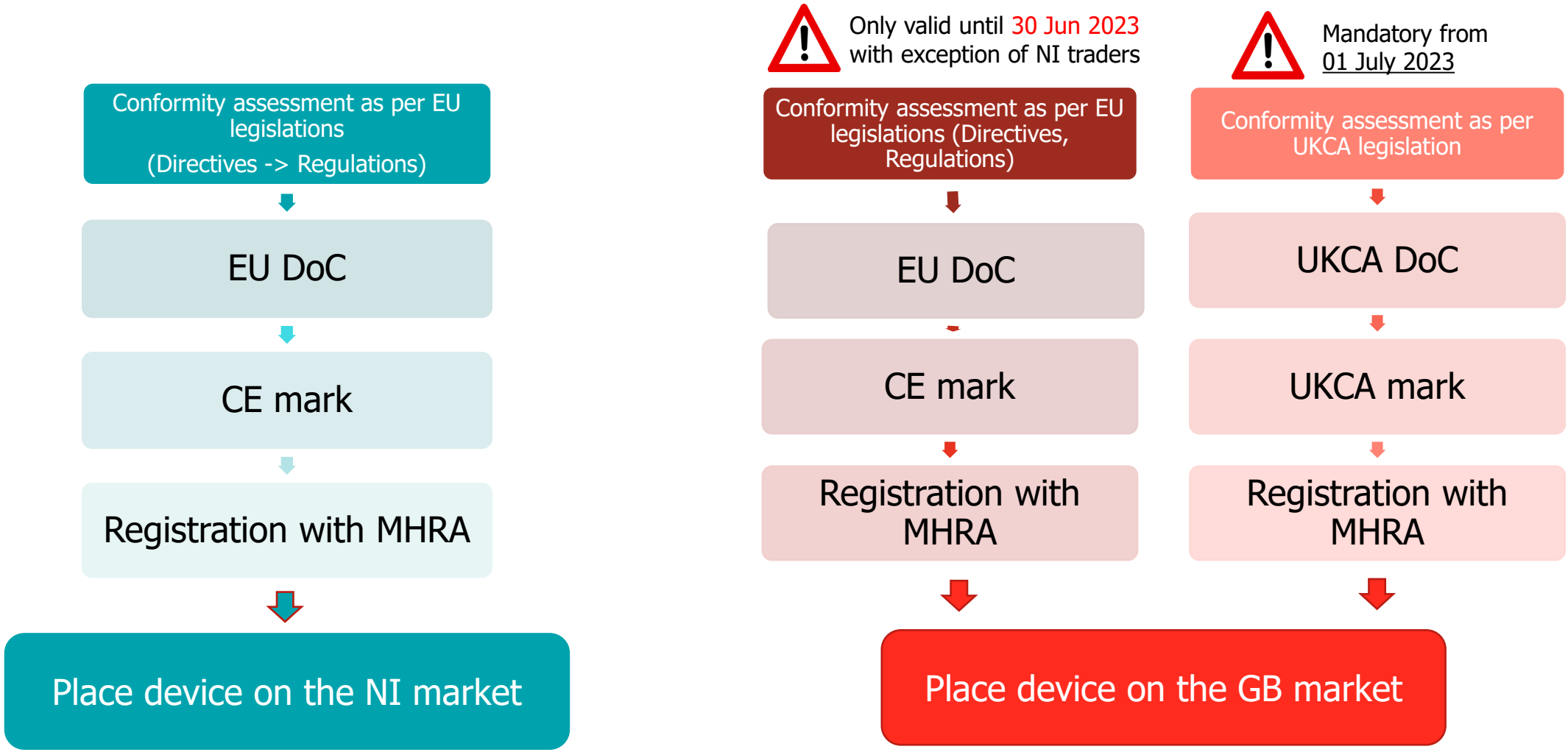
Information presented within this webinar is based on our current understanding of the applicable legislations and information available

Routes to market for NI and GB and labelling principles

Placing a device on the UK Market after 01 Jan 2021



Registration of Devices

- After 01 Jan 2021, devices must be registered with MHRA before being placed on the UK market
  - Irrespective of whether UKCA marked or CE marked
- Custom-made devices – Timelines based on their classification as per the table
- 12-month grace period will not apply to manufacturers of Class I devices and general IVDs that are currently required to register with the MHRA.

Need a UK Responsible Person if the legal manufacturer is based outside UK

Can be registered earlier

Classifications	Must be registered with MHRA from
Active implantable medical devices Class III medical devices Class IIb implantable medical devices IVD List A	01 May 2021
Class IIb non-implantable medical devices Class IIa medical devices IVD List B Self-test IVDs	01 September 2021
Class I medical devices General IVDs	01 January 2022

Grace period for registration of devices

Additional guidance on registrations - https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices

UK Responsible Person (UKRP)

Manufacturers not based in UK - To appoint UKRP 'as soon as possible' (interpreted as by 01 Jan 2021)

Only one UKRP allowed per legal manufacturer

Role could be fulfilled by the UK importer or distributor while not mandatory

Very similar responsibilities as an EU Authorised Rep under the Directives – see screenshot

Will act on behalf of manufacturer to perform specific tasks including registering devices

No symbol published (yet) for UKRP

No specific qualification criteria, but must be competent to undertake the activities required of them

Not the same as PRRC and no requirement to have a PRRC (as per MDR, IVDR)

- ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
- keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA
- in response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device
- where they have samples of the devices or access to the device, comply with any request from the MHRA to provide such samples or access to the device
- where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the MHRA to provide such samples or access, and communicate to the MHRA whether the manufacturer intends to comply with that request
- cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
- immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed
- if the manufacturer acts contrary to its obligations under these Regulations:
  - terminate the legal relationship with the manufacturer; and
  - inform the MHRA and, if applicable, the relevant Approved Body of that termination.

What product marking will get you where?

CE

GB	NI	EU
✓ Until 30 Jun 2023; NI trader exemption	✓	✓

UKCA

GB	NI	EU
✓ Can be used from 01 Jan 2021, but mandatory from 01 July 2023	✗	✗

UKCA + CE

GB	NI	EU
✓	✓	✓

UKCA + CE + UK(NI)

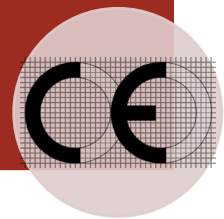
GB	NI	EU
✓	✓	✗

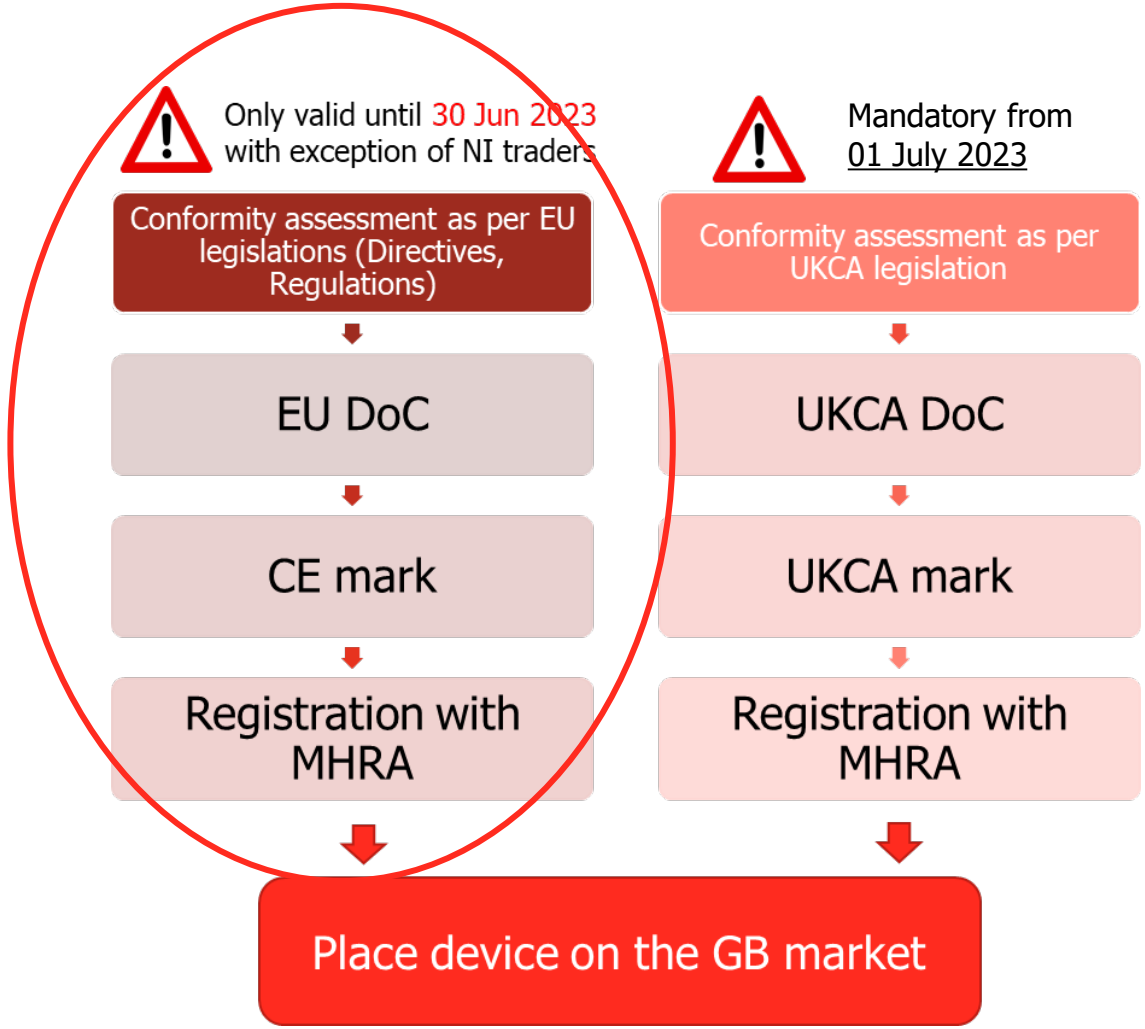
CE+UK(NI) is to be applied when a UK based CAB conducts conformity assessment against EU requirements. Devices bearing the UK(NI) mark cannot be further circulated into Europe after being placed in the NI market

General Labelling Principles – Accessing GB Market via compliance with EU legislations

- UKCA mark **not** to be used
- Manufacturers outside UK must appoint UKRP, but not mandatory to identify UKRP on labelling

Devices placed on GB market based on CE certification / CE marking

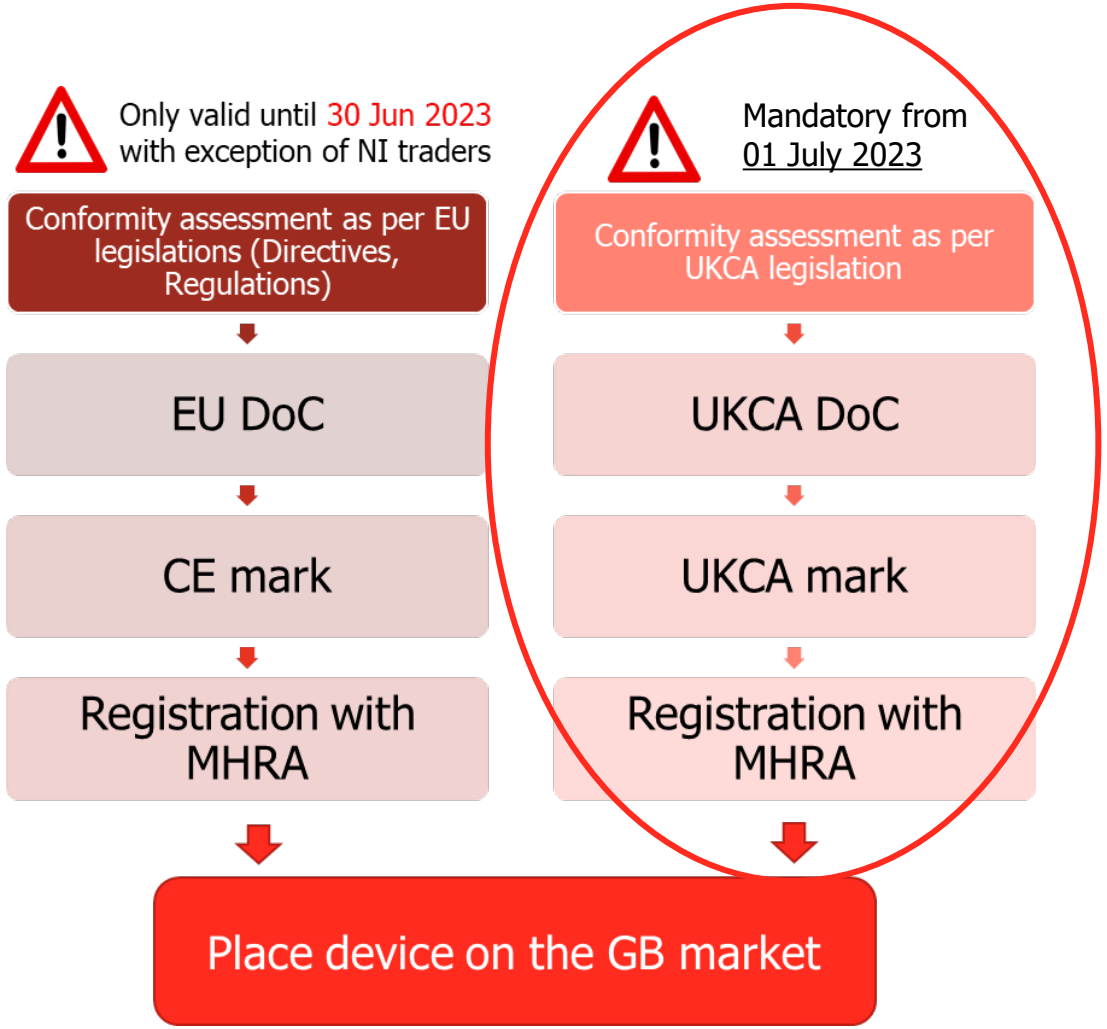




General Labelling Principles – Accessing GB Market via complying with UK legislation

- UKCA mark must be used (some exceptions for e.g Custom made devices)
- The UKAB number is to be included in case a UKAB has been involved in the conformity assessment
- Manufacturers outside UK must appoint UKRP, and identify UKRP on either labels or IFU

Devices placed on GB market based on UKCA certification / UKCA mark



BSI UKCA Conformity Assessment Model

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Scenario 1
New UKCA application with no prior certification

Full conformity assessment process

Current Directive certification processes will apply in full (as the Directives are given effect in UK law through the UK MDR 2002 - as amended)

UK specific requirements related to UKCA marking, draft DoC, UKRP, and device registrations – covered during assessments

Device drug combinations - consultations undertaken with MHRA

Devices with animal tissue derivatives with Transmissible spongiform encephalopathies (TSE) risk – Technical review by MHRA to replace the European SER commenting process

Scenario 2
UKCA application for manufacturers holding EU Directive/Regulation certificates issued by BSI NL NB 2797

Abridged conformity assessment process <u>where</u> possible

- Gather and summarise evidence from prior assessments
- Current compliance status (any outstanding Major NCs?)
- Validity of any consultations previously conducted considering any changes to the devices (for device-drug combinations and devices utilising animal tissue derivatives with TSE risk) – Specialist Review and consultations with MHRA if needed
- Review of UK specific requirements – draft DoCs, UKCA labelling and UKRP information

Additional assessments may be required in some cases

Scenario 3
UKCA application for manufacturers holding EU Directive/Regulation certificates issued by other non-BSI EU NBs

Abridged conformity assessment following principles similar to CE certificate transfer (although not a true transfer)

- Pre-Transfer Technical Documentation Review
- QMS Transfer audit – Typically 1 day
- Sampling of Technical Documentation for IIa/IIb/List B devices
- Transfer dossier reviews for each Class III/AIMD/List A devices
- Validity of any consultations previously conducted considering any changes to the devices (for device-drug combinations and devices utilising animal tissue derivatives with TSE risk) – Specialist Review and Consultations with MHRA if needed
- Review of UK specific requirements – incorporated into the above assessments

Scenario 4
Combined initial applications – UKCA + EU legislations (MDR/IVDR/ IVDD)

Combined assessments where possible

Quality Management System Audits (including Microbiology audits if required)

- Combined QMS audits
- Combined Microbiology audits
- Extra time (~0.5 day) added to the normal Stage 2 and Recertification audits to cover two sets of legislative requirements

Technical Documentation Reviews (if required)

- Combined Technical Documentation Review process for MDR+UKCA and IVDD + UKCA
- Separate reviews for IVDR and UKCA (IVDD) due to significant differences in the requirements between IVDD and IVDR
- Additional time added per device to cover two different legislations and reporting requirements (~ 0.5 day/per device selected for review)

Other elements

- Combined unannounced audits where possible. Separate audits maybe needed based on the scope differences of UKCA and EU certifications
- Separate consultations are required for each legislation for device-drug combinations
- Separate processes are required for devices containing animal tissue derivatives with TSE risk
  - UK – Technical assessment by MHRA
  - EU – SER commenting process

BSI

A Global Organization

BSI is…

A Notified Body for CE marking under 15 European Directives

Approved Body for UKCA

A Certification Body for schemes including ISO 13485, ISO 9001, ISO 14001, ISO 45001 (formerly OHSAS 18001) and ISO 27001

A recognized Conformity Assessment and Certification Body for many local market access schemes

An Auditing Organization for MDSAP

A global training provider

The UK National Standards Body

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Webinar

MDR Conformity Assessment Routes webinar

MDR - What we know

Download the presentation >

White Paper

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

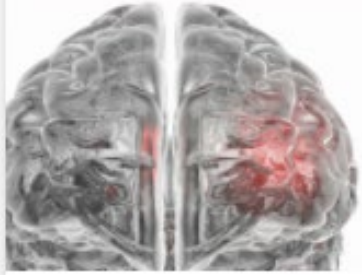
Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

BSI Trainings



Schulungen zu Medizinprodukten

- CE Kennzeichnung
- ISO 13485
- MDSAP

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Your contact for further questions

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