Post-Brexit UK legislation for medical devices

Gary Slack, SVP Medical Devices

Jayanth Katta, Senior Regulatory Lead

29 September 2020

By Royal Charter

bsi.

Agenda

- Brexit Background and timelines
- MHRA EU Exit Guidance on medical devices
  - Future UK Legislation
  - UK Approved Bodies
  - UKCA mark
  - Registration of devices
  - UK Responsible Person
- Implications for Manufacturers

- Information presented within this webinar is based on our current understanding of the Guidance published by MHRA
- Subject to change

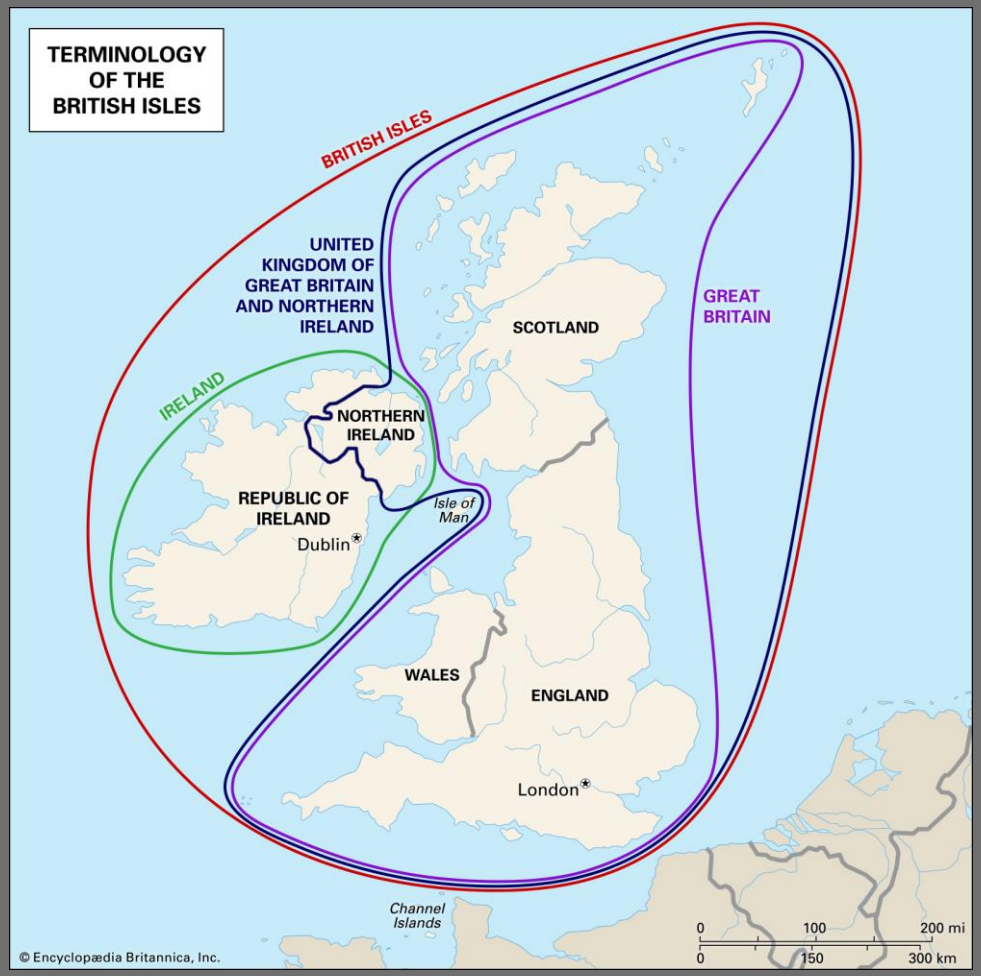
Quiz 1

- Republic of Ireland is part of:
  - ❑Northern Ireland
  - ❑Great Britain
  - ❑United Kingdom
  - ❑None of the above

Quiz 1

- Republic of Ireland is part of:
  - ❑ Northern Ireland
  - ❑ Great Britain
  - ❑ United Kingdom
  - ☑ None of the above

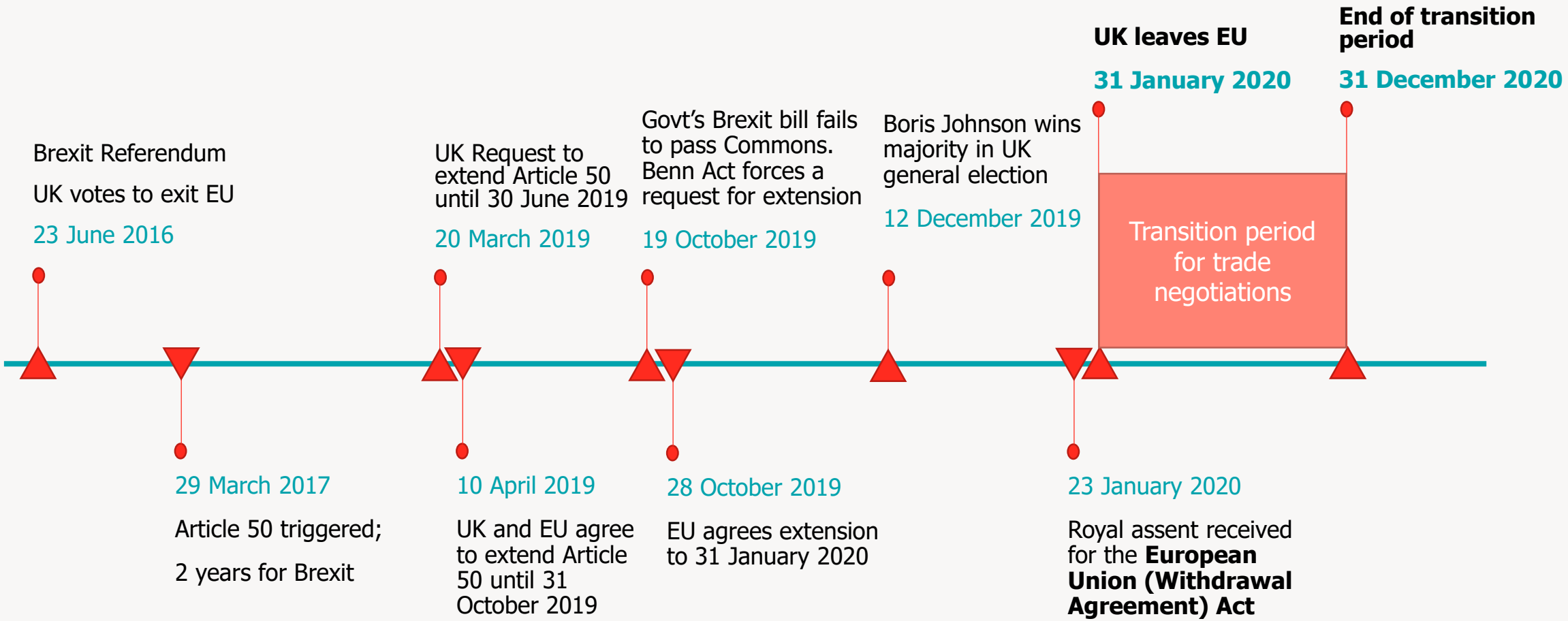
RoI is part of the EU



Source: Encyclopaedia Britannica

Brexit Background and Timelines

Brexit Timeline - Key Milestones



EU Withdrawal Agreement
Key Sections

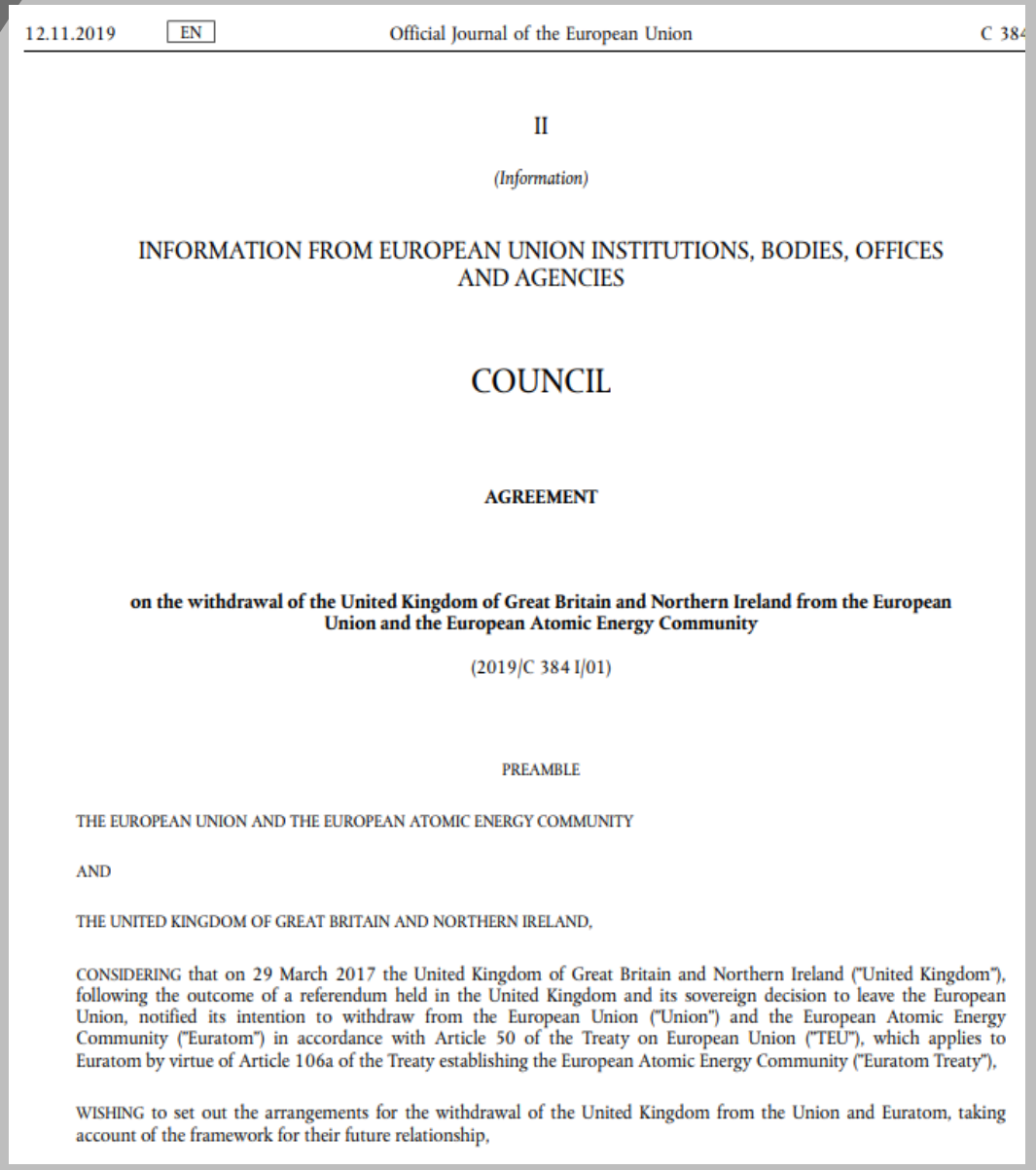
- Common provisions
- Citizens' rights
- Separation issues
- Transition period
- Financial settlement
- Governance
- Protocol on N.I
- Protocol on Cyprus
- Protocol on Gibraltar

EU treats the UK as if it were a Member State, but UK cannot participate in the EU institutions and governance structures;

Negotiations for a future partnership

To prevent hard border between NI and RoI;
Protect the Good Friday agreement;
Safeguard integrity of EU single market

N.I will continue to follow EU Rules from 01 Jan 2021 while the rest of UK will not



12.11.2019 EN Official Journal of the European Union C 384

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

COUNCIL

AGREEMENT

on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community

(2019/C 384 I/01)

PREAMBLE

THE EUROPEAN UNION AND THE EUROPEAN ATOMIC ENERGY COMMUNITY

AND

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

CONSIDERING that on 29 March 2017 the United Kingdom of Great Britain and Northern Ireland ("United Kingdom"), following the outcome of a referendum held in the United Kingdom and its sovereign decision to leave the European Union, notified its intention to withdraw from the European Union ("Union") and the European Atomic Energy Community ("Euratom") in accordance with Article 50 of the Treaty on European Union ("TEU"), which applies to Euratom by virtue of Article 106a of the Treaty establishing the European Atomic Energy Community ("Euratom Treaty"),

WISHING to set out the arrangements for the withdrawal of the United Kingdom from the Union and Euratom, taking account of the framework for their future relationship,

Future Timetable

30 June 2020	The deadline for the UK to request an extension of the transition period beyond 2020. The government has legislated to prohibit an extension being requested.
July-October 2020	Further UK-EU negotiating rounds?
October 2020	The EU hopes to conclude negotiations ahead of the European Council summit on 15-16 October, to provide sufficient time to ratify any agreement in both the European Parliament and the British parliament.
15-16 October	European Council summit
31 October 2020	Taking into account the time needed to ratify a deal, Michel Barnier has stated a full legal text would be needed by this date – at the latest.
November-December 2020	Conclusion/ratification of agreement?
23-26 November 2020	Possible dates for European Parliament consent vote on UK-EU agreement.
31 December 2020	Unless there is a decision to extend it, this is when the transition period established by the Withdrawal Agreement will end. If a trade deal is not in place, the UK will fall back on to WTO rules.

https://commonslibrary.parliament.uk/research-briefings/cbp-7960/

MHRA Guidance – Future UK medical device legislations

bsi.

Information presented within this webinar is based on our current understanding of the Guidance

Subject to change - Parts of the guidance may be updated based on the outcomes of the trade negotiations with EU

Different rules for GB and NI

Specific to medical devices. **Some provisions are different compared to other products**

Many unknowns – More guidance expected to be published in several areas

Guidance

Regulating medical devices from 1 January 2021

What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets from 1 January 2021.

Published 1 September 2020
From: Medicines and Healthcare products Regulatory Agency

New rules for January 2021

The UK has left the EU, and the transition period after Brexit comes to an end this year.

This page tells you what you'll need to do from 1 January 2021. It will be updated if anything changes.

For current information, read: **Medical devices regulation and safety**

You can also read about the transition period.

https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021#UKCA

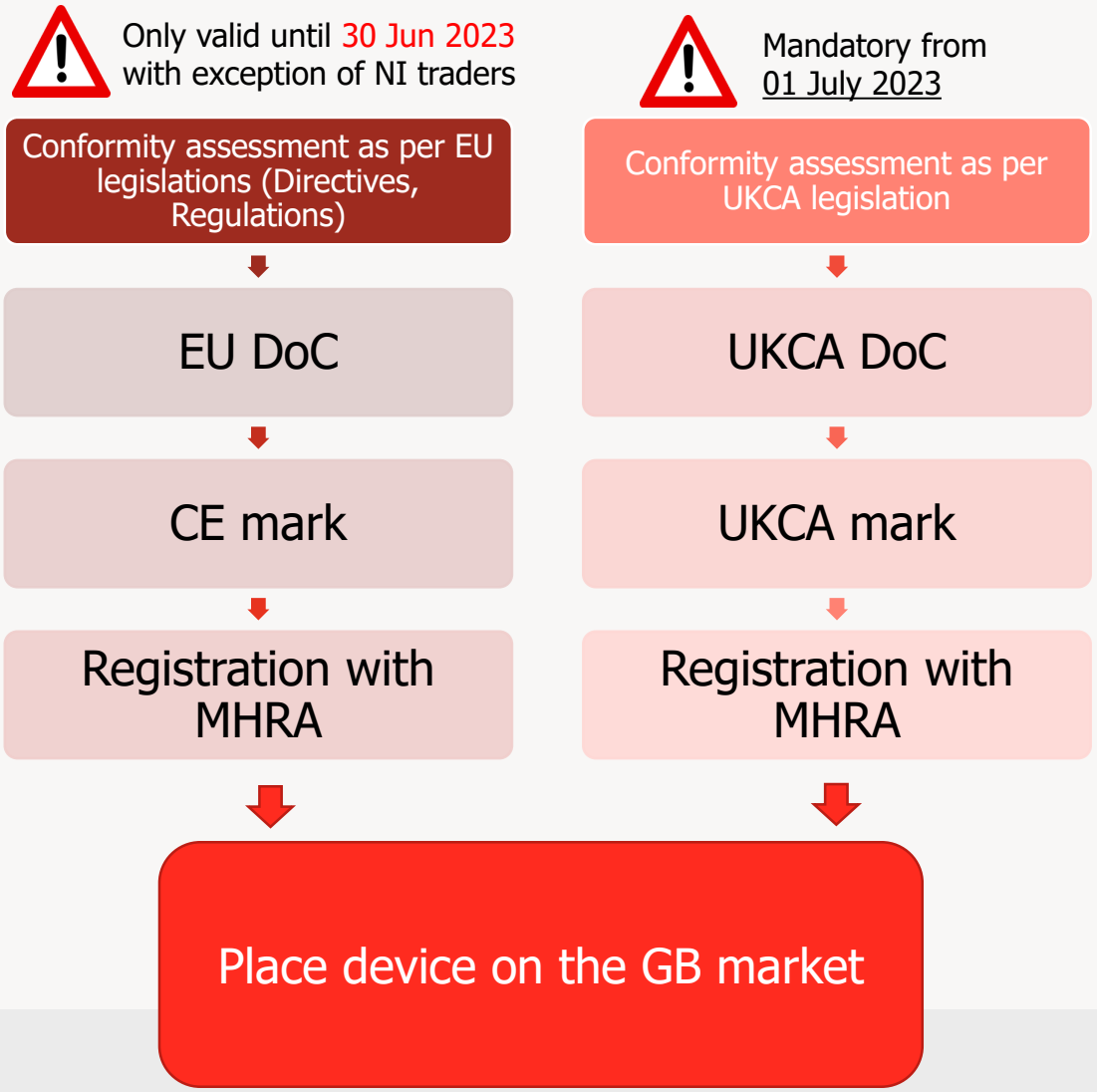
Headlines

- GB will recognise EU CE marking and EU NB issued CE certificates (both Directives and Regulations) until 30 June 2023*
  - Ensures a smooth transition to the new UKCA regulatory framework
  - Ensures market access to medical devices

- In parallel, from 01 Jan 2021 a new route to market and product marking (UKCA) will be available for manufacturers wishing to place a device on the Great Britain market

*Transition times for accepting CE marking (and other requirements) are different for medical devices compared to many other products covered by other legislations most of which have a 1-year transition time

Placing a device on the GB Market after 01 Jan 2021



UKCA Legislation

After the transition period GB will continue to operate under MDD, AIMDD and IVDD as incorporated into UK law (UK MDR 2002) and in the form they exist on 01 Jan 2021

Soon, UK MMD Bill (Medicines and Medical Devices Bill 2019-21) will introduce secondary legislation to establish a new stand-alone regulatory framework for GB

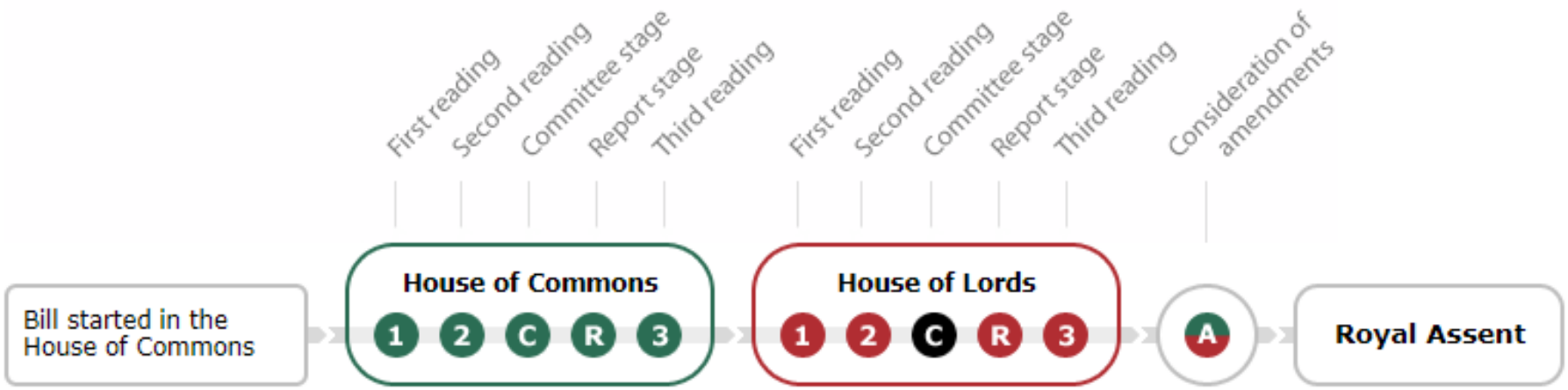
MDR and IVDR will not apply in GB as their dates of application are beyond the end of the transition period and hence are not automatically retained EU law

But they will apply in NI due to the NI protocol

UK MMD 2019-21

A Bill to confer power to amend or supplement the law relating to human medicines, veterinary medicines and medical devices; make provision about the enforcement of regulations, and the protection of health and safety, in relation to medical devices; and for connected purposes.

Progress of the MMD Bill (as of 24th Sep 2020)



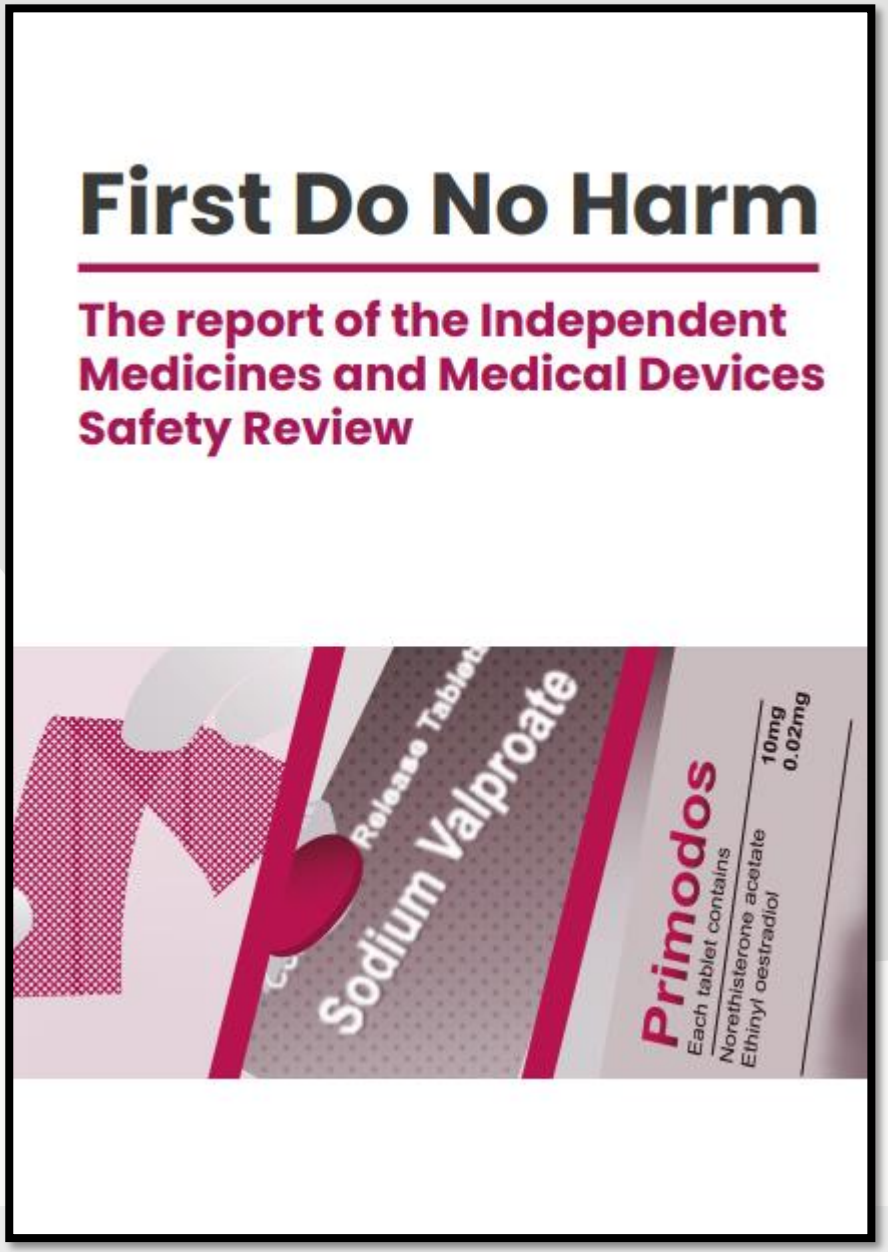
Last events	Next event
2 2nd reading (Hansard): House of Lords 2 September, 2020 | 02.09.2020	C Committee stage: House of Lords | Date to be announced

UK MMD Bill 2019-21

Expected to address the recommendations from the Cumberlege Report (Independent Medicines and Medical Devices Safety Review)

Several unknowns

- Timeline for completion of the Bill (maybe by the end of 2020?!)
- Timeline for the publication of the new regulatory framework
- What will the new regulatory framework look like?



https://www.immdsreview.org.uk/Report.html

Role of MHRA

- Will continue to perform market surveillance of medical devices on the UK market
- Responsible for the designation and monitoring of UK Conformity Assessment Bodies for medical devices

UK Approved Bodies – To conduct conformity assessment against UKCA requirements

Must be based in the UK

On 01Jan2021,

UK NBs -> UK Approved Bodies

Current designations of UK Notified Bodies to roll over automatically – No additional designation process

UKABs to retain their NB number (e.g. BSI UK will be 0086 even under UKCA)

EU NANDO -> UK MCAB

BSI fully committed to being a UKAB

Only UKAB with full scope for all three Directives

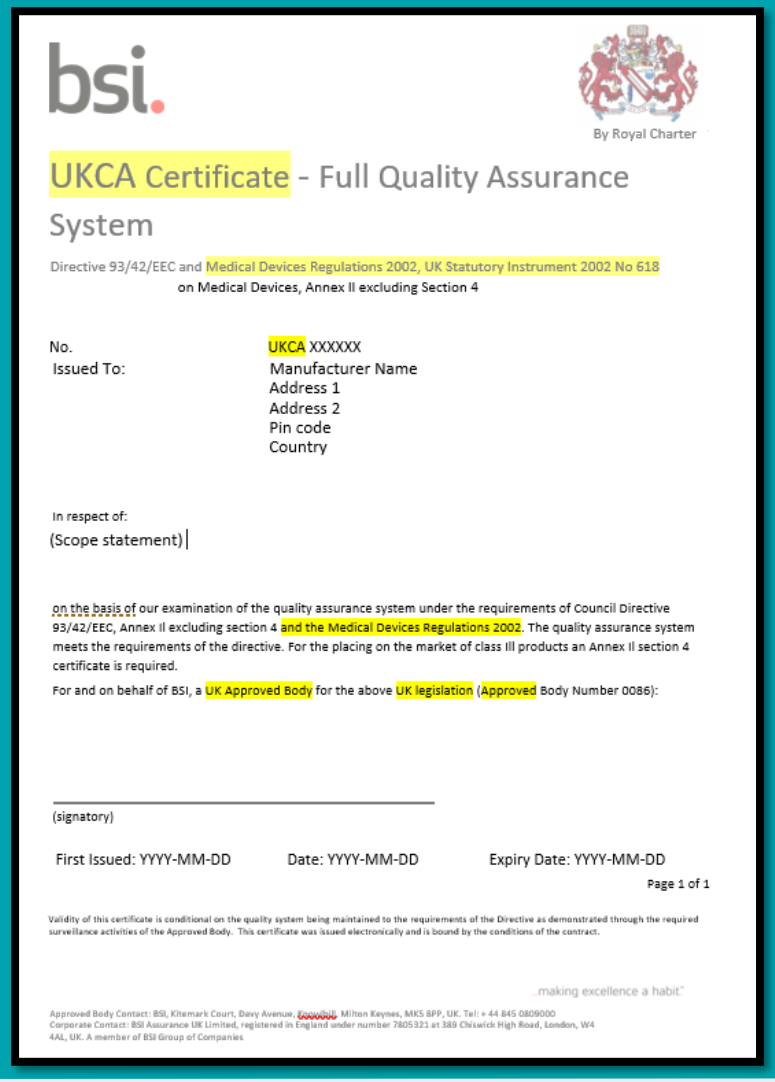
UK Approved Bodies – UKCA certificates

UKCA Prefix on certificates

Will need to refer to the UK legislation MDR 2002

Any CE certificates issued prior to 01 Jan 2021 by UK based NBs will continue to remain valid after 01 Jan 2021 for GB market

- Changes to, renewal of certificate after 01 Jan 2021 will need to be processed as UKCA certificates



bsi.

By Royal Charter

UKCA Certificate - Full Quality Assurance System

Directive 93/42/EEC and Medical Devices Regulations 2002, UK Statutory Instrument 2002 No 618
on Medical Devices, Annex II excluding Section 4

No. UKCA XXXXXX
Issued To: Manufacturer Name
Address 1
Address 2
Pin code
Country

In respect of:
(Scope statement)

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4 and the Medical Devices Regulations 2002. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a UK Approved Body for the above UK legislation (Approved Body Number 0086):

(signatory)

First Issued: YYYY-MM-DD Date: YYYY-MM-DD Expiry Date: YYYY-MM-DD

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Approved Body. This certificate was issued electronically and is bound by the conditions of the contract.

...making excellence a habit.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 0809000
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK. A member of BSI Group of Companies

Certificate template subject to change

UKCA mark – "UK Conformity Assessed" mark

- Applies from 01 Jan 2021
- Placed on devices when the UKCA requirements have been met
- Not recognised in EU, EEA or NI
- Mandatory from 1 July 2023 to place a device on the GB market; But will not apply to NI traders (to be clarified in the future)
- Additional details and proportions etc specified - https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021
- Manufacturer who has met both CE and UKCA requirements can dual mark their devices
- Manufacturers of Class I medical devices and general IVDs will be able to self-declare their conformity against Part II and Part IV of the UK MDR 2002 (in the form in which they exist on 1 January 2021), before affixing a UKCA mark and placing the device on the Great Britain market.

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

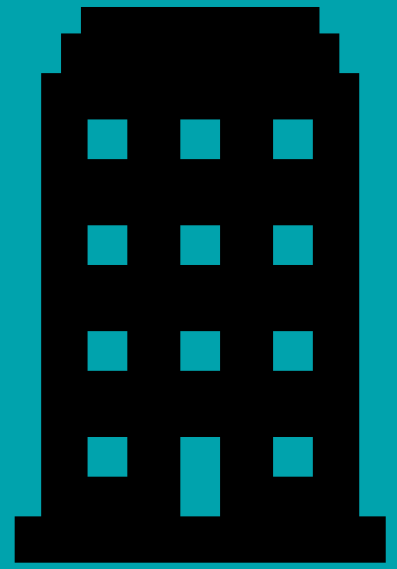
Classifications	Deadline for Registration
Active implantable medical devices Class III medical devices Class IIb implantable medical devices IVD List A	30 April 2021 (4 months)
Class IIb non-implantable medical devices Class IIa medical devices IVD List B Self-test IVDs	31 August 2021 (8 months)
Class I medical devices General IVDs	31 December 2021 (12 months)

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

- To be appointed by manufacturers not based in UK
- Will act on behalf of manufacturer to perform specific tasks including registering devices
- Role could be fulfilled by the UK importer while not mandatory (to be confirmed)
- Very similar responsibilities as an EU Rep under the Directives – see MHRA guidance for full details
- Grace periods for appointing UKRP – aligned to the grace period for registration of devices
- No symbol published (yet) for UKRP
- No requirement for PRRC (as per MDR, IVDR)



Post-market surveillance and Vigilance

- Manufacturers responsible for PMS and vigilance reporting for devices placed in the UK market
- Vigilance reports for incidents in UK to be submitted to MHRA
- Manufacturer will need to ensure their device meets appropriate standards of safety and performance for as long as it is in use.
- Further guidance to be provided by MHRA on whether the current EU MIR form can be used or a UK specific form for vigilance reporting will be released after 01 Jan 2021

Other considerations

EU REACH → UK REACH		(https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations)
EU standards → BS Standards		Same in substance and with same reference, but with BS prefix
EU DoC → UK DoC		Largely same content as the corresponding EU DoC, but specifies UK legislation and UK standards instead of the corresponding EU references
CTS for IVDs → CTS for IVDs		Common Technical Specifications (CTS) will become Common Specifications in EU under IVDR; They will continue to remain as CTS in the UK
Reference Labs for IVD Annex II List A devices after May 2022 when they become EURLs	→ ?	To be confirmed

Labelling transitions

Non-UK manufacturer placing devices on GB market

- If product placed on GB market using CE mark – not mandatory to re-label to add UKCA mark or UK Responsible Person information until the 30 June 2023
- Devices that are dual labelled with both the CE and UKCA marks will continue to be accepted on the Great Britain market after 1 July 2023.

UK manufacturer (or non-UK manufacturer with GB based EU Rep) placing devices in EU/EEA

- Need CE certificate issued by an EU NB to access EU market
- Need an EU Rep based in EU/EEA/NI
- No additional guidance from EU on labelling transition – prepare to implement by 01 Jan 2021

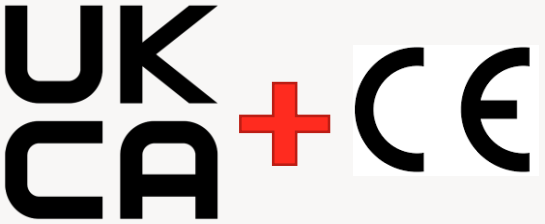
Northern Ireland – Special Considerations

- EU MDR and IVDR will apply from 26 May 2021 and 26 May 2022 respectively
- Even after 01 July 2023, CE mark will continue to be needed for devices placed on the Northern Ireland market and EU rules will need to be met.
- CE certificates issued prior to 01 Jan 2021 by UK NBs will not be recognised after that date for NI market
- UK Approved Bodies will be able to conduct conformity assessments for NI market under the Directives (UK MDR 2002)
    - UK(NI) mark to accompany, but not replace, the CE mark.
    - Products carrying both the CE mark and UK(NI) mark cannot be placed on the EU market.
    - UKCA marked devices will not be accepted on the Northern Ireland market unless accompanied by the CE or CE UK(NI) mark.
- Specific Registration and UKRP requirements apply for NI
- Full details: https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021#NI
- Further guidance to be issued by Gov on NI

What product marking will get you where?

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

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



GB	NI	EU
✓	✓	✓

Additional guidance/clarity needed on UK (NI) mark

Implications for Manufacturers

I’m a Manufacturer with CE certification from a UK NB (such as BSI NB 0086)

CE certificates will not be valid for NI or EU after 01 Jan 2021

CE certificates will continue to be valid GB after 01 Jan 2021

- At the first re-issue (change or renewal), they will need to be converted to UKCA certificates
- Once UKCA certificate issued, labelling will have to transition to UKCA mark (to be confirmed)

No need to extend/amend the expiry dates on these certificates

If early renewal is applied for – full 5 years validity can be given

- however the certificate will need to be re-issued as a UKCA certificate from 01 Jul 2023

All surveillance activities to continue as per existing arrangements, but UKCA requirements related to registrations, UKRP etc will be checked during future NB audits

I’m a manufacturer with CE certification from an EU NB (such as BSI NL 2797)

You will be able to access GB (until June 2023), NI and EU markets with the CE certificates	For accessing the GB market after 01 Jan 2021:
• GB market will need UKCA mark after 01 July 2023	• Device registrations with MHRA • Appoint UKRP • Not mandatory to add UKRP information to labelling until June 2023

If the manufacturer is in GB, in order to access the EU market after 01 Jan 2021:

- Appoint an EU Rep
- Work with your NB to get your CE certificates reissued with the EU Rep information
- Prepare to have updated labelling by 01Jan2021 to mitigate risk
- Future NB surveillance audits will verify the appointment of EU Rep

https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_industrial_products.pdf

UKCA Applications/certification

When can we apply for UKCA certification?	• After 01 Jan 2021
Will BSI UK be ready to accept UKCA applications from 01 Jan 2021?	• Depends on when the UK legislation will be finalised and the time it allows BSI to prepare • Further communications planned
We have a CE certificate (Directives or Regulations) issued by BSI NL (2797). Can we get a UKCA certificate based on the CE certificate?	•Yes, a formal application will be required •In the short term while UKCA is based on Directives: No additional conformity assessments (To be confirmed) •In the long term when new regulatory frame-work is in effect – To be determined
We have a CE certificate (Directives or Regulations) issued by another EU NB. Can we get a UKCA certificate from BSI based on the CE certificate?	• Yes, a formal application will be required • In the short term when UKCA is based on Directives: Some level of conformity assessments will be required (To be confirmed) • In the long term when new regulatory framework is in effect – To be determined

Remember that CE mark is accepted in GB until June 2023

Quiz 2

- As a manufacturer I will be interested in applying for UKCA certification:
  - ❑In 2020
  - ❑In 2021
  - ❑In 2022
  - ❑In 2023
  - ❑Will not be applying

Some of the Unknowns..

Devices not covered by Directives, but covered by MDR/IVDR

NI Trader arrangements, and definition of an NI Trader

EUDAMED access to UK is unlikely!! UK to have its own equivalent

UK's secondary legislation as enabled by the MMD bill

More resources: https://www.bsigroup.com/en-GB/medical-devices/

By Royal Charter