UKCA- Medical Devices

Are you ready for the future?

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Agenda

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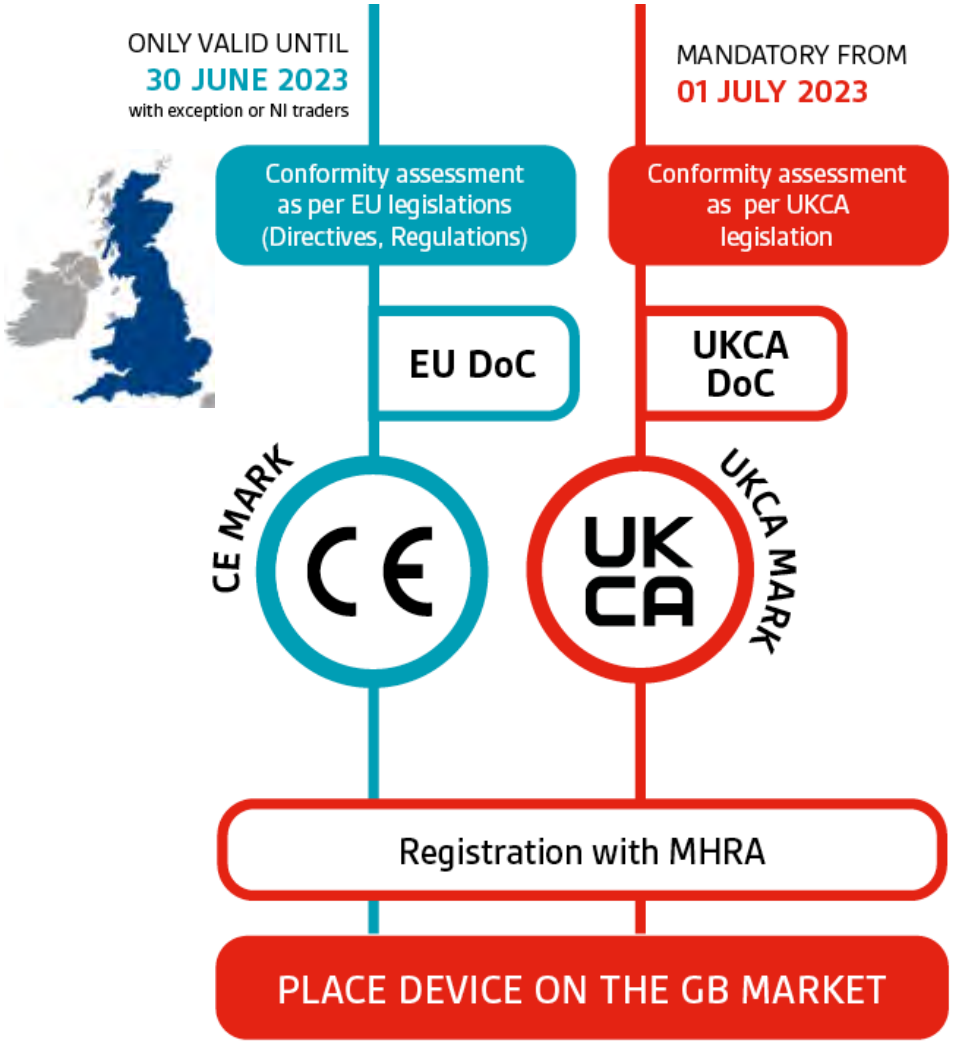
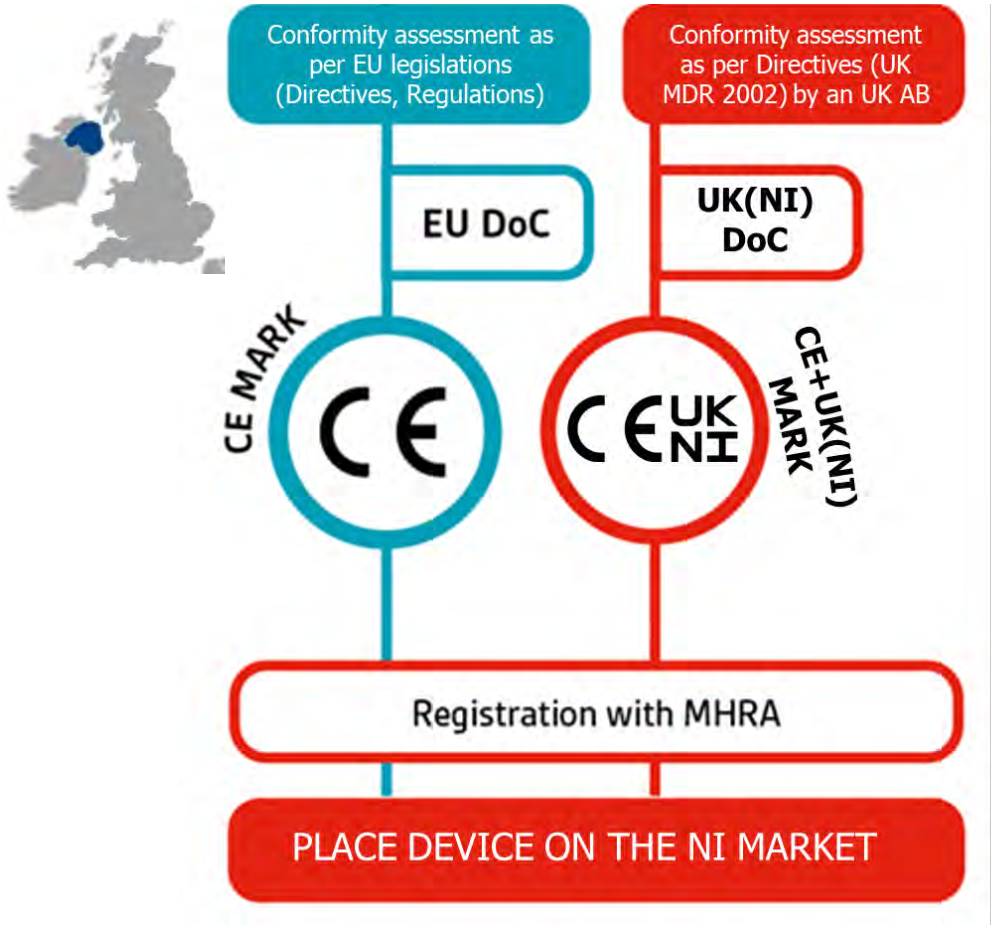
- Information presented within this webinar is based on our current understanding of the applicable legislations and information available

Welcome

Process to UKCA Marking

Placing a device on the UK Market





BSI Process to UKCA Marking

Manufacturers with EC certificates issued by BSI UK 0086

New applications for UKCA certification (with no prior certification held by Manufacturer)

New applications for UKCA certification based on EC certification (Directives or Regulations) issued by BSI NL 2797

New applications for UKCA certification based on EC certification (Directives or Regulations) issued by another EU NB (not BSI NL 2797)

Combined applications: UKCA certification (MDD,AIMDD) (with BSI UK) + MDR (with BSI NL)

Combined applications: UKCA certification (IVDD) (with BSI UK) + IVDD (with BSI NL)

Combined applications: UKCA certification (IVDD) (with BSI UK) + IVDR (with BSI NL)

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UKCA conformity assessment model – General Principles

Manufacturers with EC certificates issued by BSI UK 0086

- Certificates to be converted to UKCA certificates at the next re-issue or by the 30th June 2023 whichever comes first.

New applications for UKCA certification (with no prior certification held by Manufacturer)

- Follow current MDD/IVDD/AIMDD processes but account for the UK specific requirements where relevant.

New applications for UKCA certification based on EC certification (Directives or Regulations) issued by BSI NL 2797

- Abridged process to recognise the conformity assessments already carried out by BSI NL along with coverage for UK specific requirements. (Exception – IVDR)

New applications for UKCA certification based on EC certification (Directives or Regulations) issued by another EU NB (not BSI NL 2797)

- Follow the principles of Transfer along with coverage for UK specific requirements.

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UKCA conformity assessment model – General Principles

Combined applications: UKCA certification (MDD,AIMDD) (with BSI UK) + MDR (with BSI NL)
Combined applications: UKCA certification (IVDD) (with BSI UK) + IVDD (with BSI NL)

- Follow MDR (or IVDD) certification processes generally, along with coverage for UK specific requirements.
- Combined QMS audits, Combined Micro audits, Combined Technical documentation assessments

Combined applications: UKCA certification (IVDD) (with BSI UK) + IVDR (with BSI NL)

- Combined QMS audits, Combined Microbiology audits, but **stand-alone** Technical documentation reviews under IVDR, IVDD

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Consultations under EU Reg.722/2012 (animal tissues) and 2001/83/EC (medicinal products)

UKCA applications based on EC certificates	Combined initial applications for UKCA and EC certification	Animal tissue derivatives with TSE-risk
BSI will contact the MHRA asking if additional consultation is required, irrespective of whether the previous consultation carried out by Manufacturers as part of the CE marking has been done with the MHRA or with another Competent Authority	Separate consultations are required under the UKCA legislation (with MHRA) and under the EU legislations with the appropriate EU Competent Authority.	For UKCA applications of devices utilising animal tissue derivatives with TSE-risk, a technical assessment is conducted by MHRA

Lessons Learnt

Poll

Are dual CE + UKCA marked devices allowed to be placed onto the GB market?

Yes

No

UKCA – General Labelling Principles

CE | GB NI EU

Until 30 June 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~~

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

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

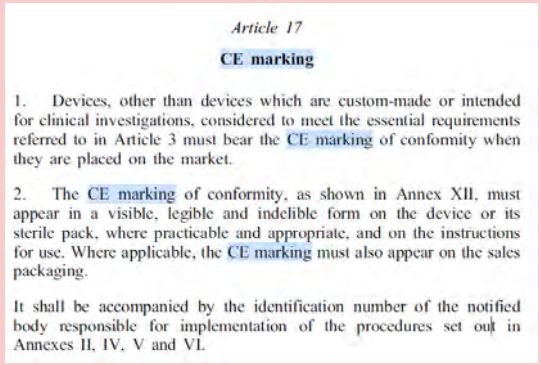
Devices placed on GB market based on UKCA certification/UKCA mark

- **UKCA mark** must be used (some exceptions for e.g. Custom made devices)
- Manufacturers outside UK must appoint UKRP, and **identify UKRP** on either labels or IFU

The UKAB number is to be included in case a UKAB has been involved in the conformity assessment

UKCA 0000

UKCA MARK ON PACKAGING



Article 17

CE marking

1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.

2. The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on the sales packaging.

It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.

The UK Regulations provide that a device or its sterile pack bear the UKCA marking where practical and appropriate.

They also provide that a UKCA marking must be affixed to any sales packaging for the device AND the instructions for use for the device.

The same principles of the EU Directives can be applied to UKCA.

The requirement states "*...where practical and appropriate, that device or its sterile pack bears a UK marking...*". The manufacturer must justify their choice of whether the UKCA mark is going on the device or the pack or both based on the type of device. The principle is similar to that of CE marking.

Is the UKCA mark on the packaging enough or must you apply the UKCA mark to the product itself?

The UKCA marking of general medical devices is covered in the UK Medical Regulations 2002 (SI 2002 No 618, as amended) under regulation 10.

Will the UKCA mark have to be applied on all levels of packaging? Or only on the outer level?

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How many UK RP are allowed per legal manufacturer?

- One per each device/device family
- Only one per legal manufacturer
- As many as the legal manufacturer wishes

UKRP ON LABELLING

UKRP should be assigned for manufacturers outside of UK

Only 1 UKRP is allowed per legal manufacturer

Follow legislative requirements for non-harmonised symbols

No symbol published (yet) for UKRP

The name and address of the UKRP must be included on the product labelling or the outer packaging, or the instructions for use in cases where the UKCA marking has been affixed.

Where shall the UKRP information be labelled?

Designated standards

Three lists of designated standards for medical devices have been published. These lists of standards apply to:

- Medical devices
- Active implantable medical devices
- In vitro diagnostic medical devices

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.

National Annex (NZ)

National Annex NZ
(informative)

Relationship between this British Standard and the Conformity Assessment Requirements of the Medical Devices Regulations 2002 (S.I. 2002 No. 618, as amended) (UK MDR 2002) aimed to be covered

This British Standard may be used to provide voluntary means of conforming to particular requirements of the UK MDR 2002 ('the Regulations'), as amended.

Once this standard is cited in the official designated standards list for medical devices, compliance with the normative clauses of this standard given in Tables NZ.1, NZ.2 and NZ.3 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding conformity assessment requirements stated in the annexes of Directives 90/385/EEC on active implantable medical devices, 93/42/EEC on medical devices and 98/79/EC on in vitro diagnostic medical devices as referred to by the Regulations as shown in the tables.

Table NZ.1 — Correspondence between this British Standard and Annexes referenced in Part III (AIMDs) of the UK MDR 2002

Paragraph of Directive 90/385/EEC referred to by the UK MDR 2002	Clause(s)/Subclause(s) of this BS	Remarks/Notes
Annex 2 - 3.1, 1st sentence		Not covered.
Annex 2 - 3.1, 2nd sentence, 1st indent		Not covered.
Annex 2 - 3.1, 2nd sentence, 2nd indent	4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5	Covered. The documentation required in this British Standard covers the quality system documentation meant in 3.2 of Annex 2 when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.

Legislative References

QMS and Technical Documentation (DoC included) must cite the proper UK legislative references

Be aware of UK designated standards and state of the art (ER 2 MDD/IVDD, ER 6 AIMDD)

Reference to UK equivalent horizontal legislations, i.e. PPE, Machinery

Legislative References

UK legislation		EU legislation
UNDER PREPARATION the UK version of Commission Recommendation 2013/473/EU – on unannounced audits and NB assessments		
Regulation 10 (MD), Regulation 24 (AIMD) and Regulation 36 (IVD) of the UK MDR 2002	Marking	Articles 17 (MDD), 12 (AIMDD), 16 (IVDD), 20 (MDR) and 18 (IVDR)
Regulation 14 of the UK MDR 2002	Systems and procedure packs	Articles 12 (MDD) and 22 (MDR)
Regulation 722/2012 (transposed into UK law with the same reference number)	Animal tissue with TSE risk	Regulation 722/2012
Regulation EU 207/2012 (transposed into UK law with the same reference number)	Electronic IFUs	Regulation (EU) 2021/2226
Regulation 7 of the UK MDR 2002	Reclassification of hip, knee and shoulder joint replacements	Directive 2005/50/EC

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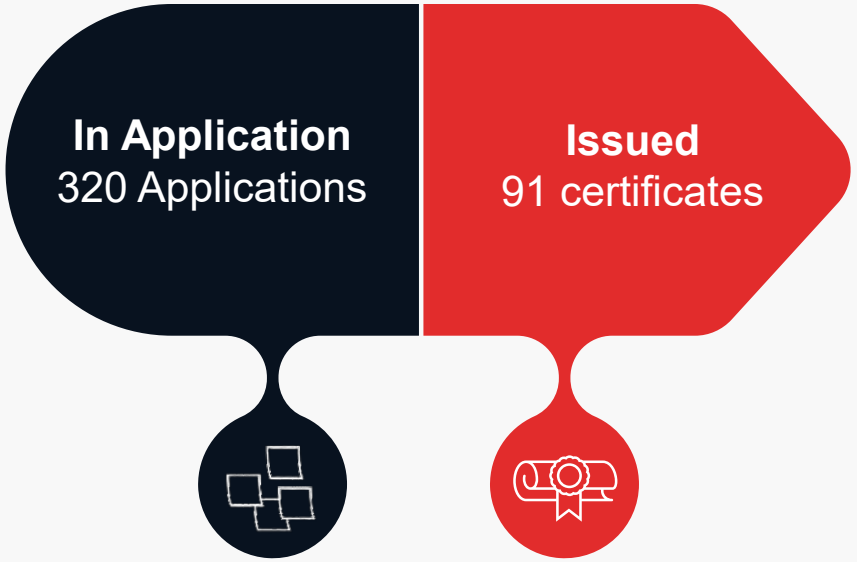
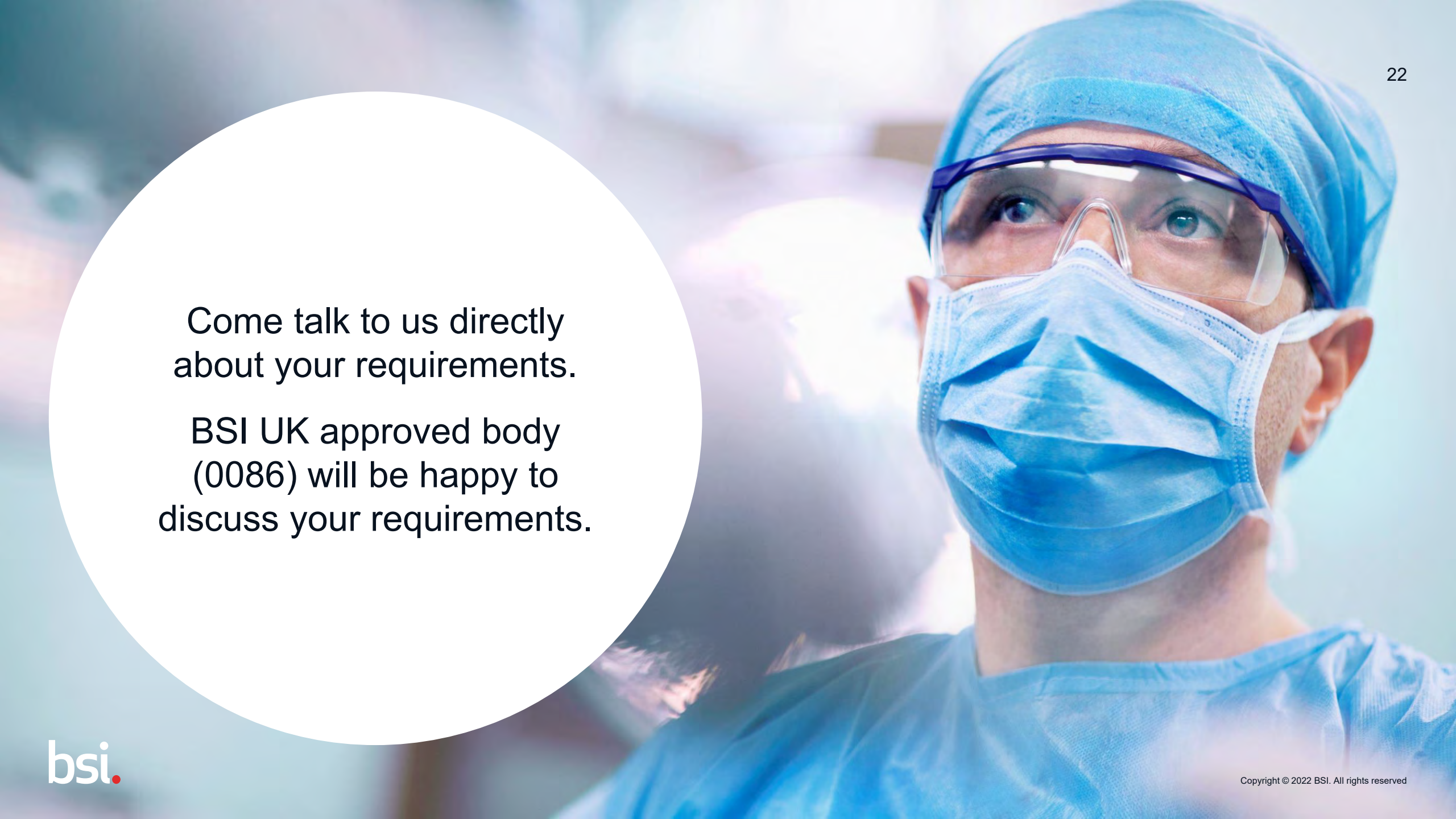
How Can BSI help you?

Current status AB0086





Come talk to us directly about your requirements.

BSI UK approved body (0086) will be happy to discuss your requirements.

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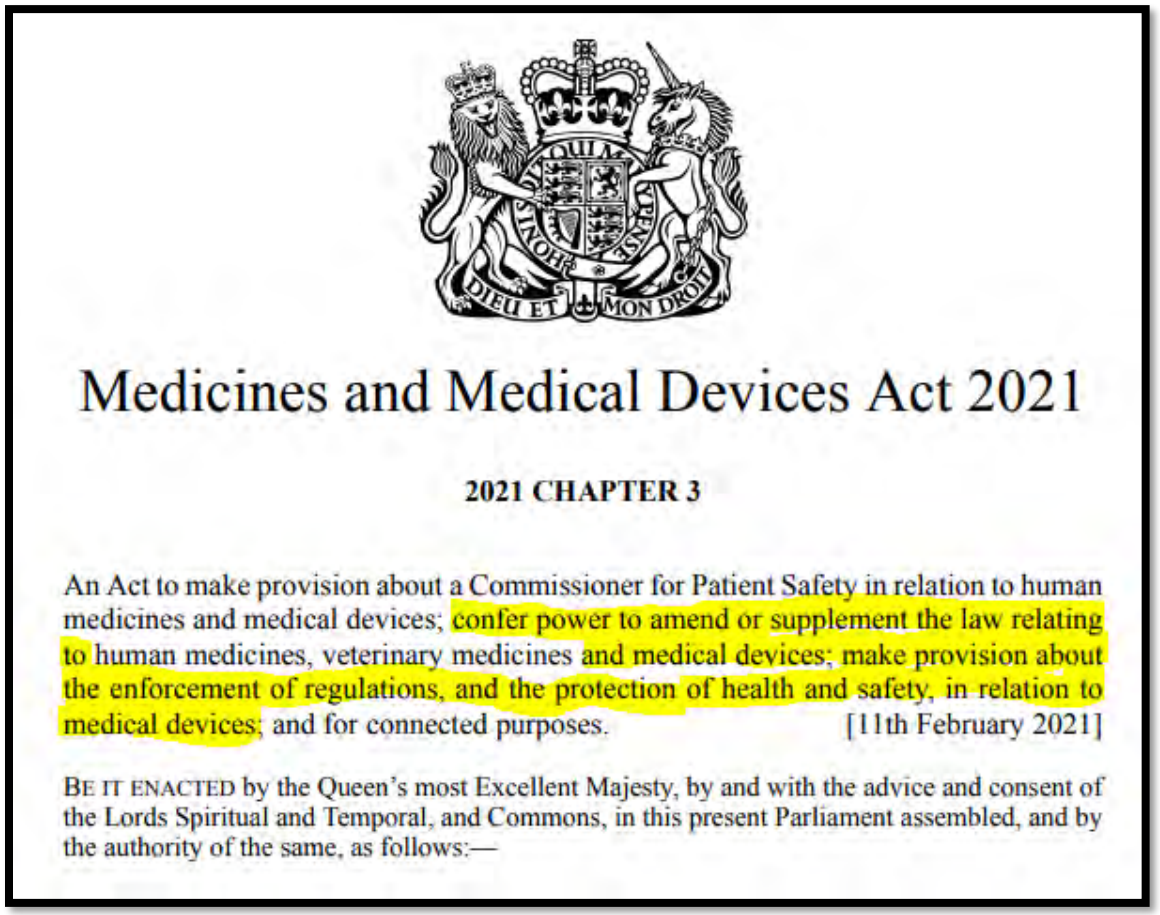
Future Legislation

The Future

New legislative framework to be introduced in UK via the MMD Act 2021 to amend or supplement UK MDR 2002



Medicines and Medical Devices Act 2021

2021 CHAPTER 3

An Act to make provision about a Commissioner for Patient Safety in relation to human medicines and medical devices; 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. [11th February 2021]

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

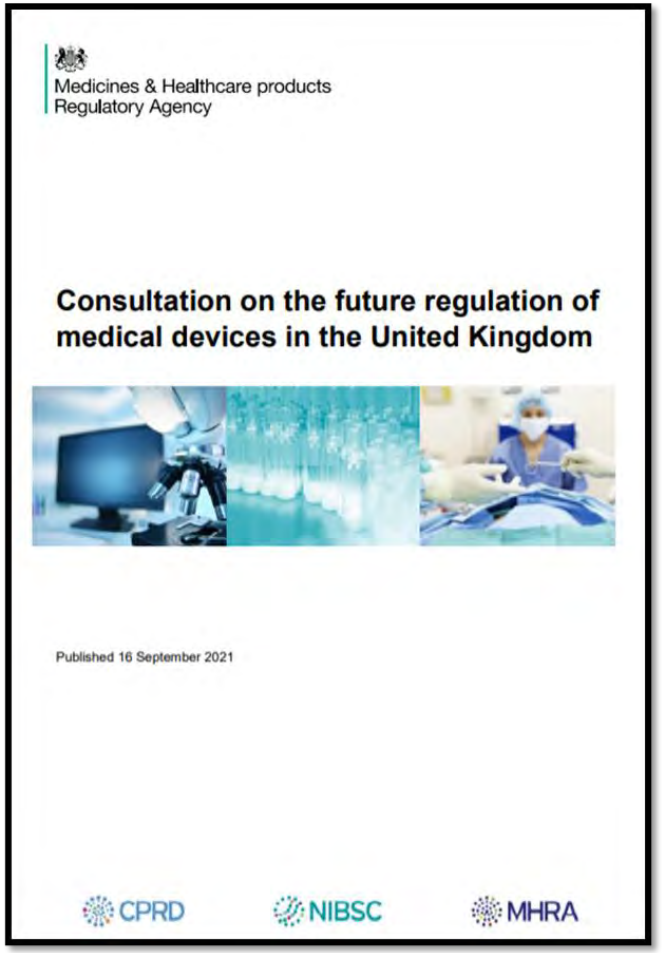
MHRA consultation on the future regulation of medical devices

16 Sep 2021 – 25 Nov 2021

Our Aims

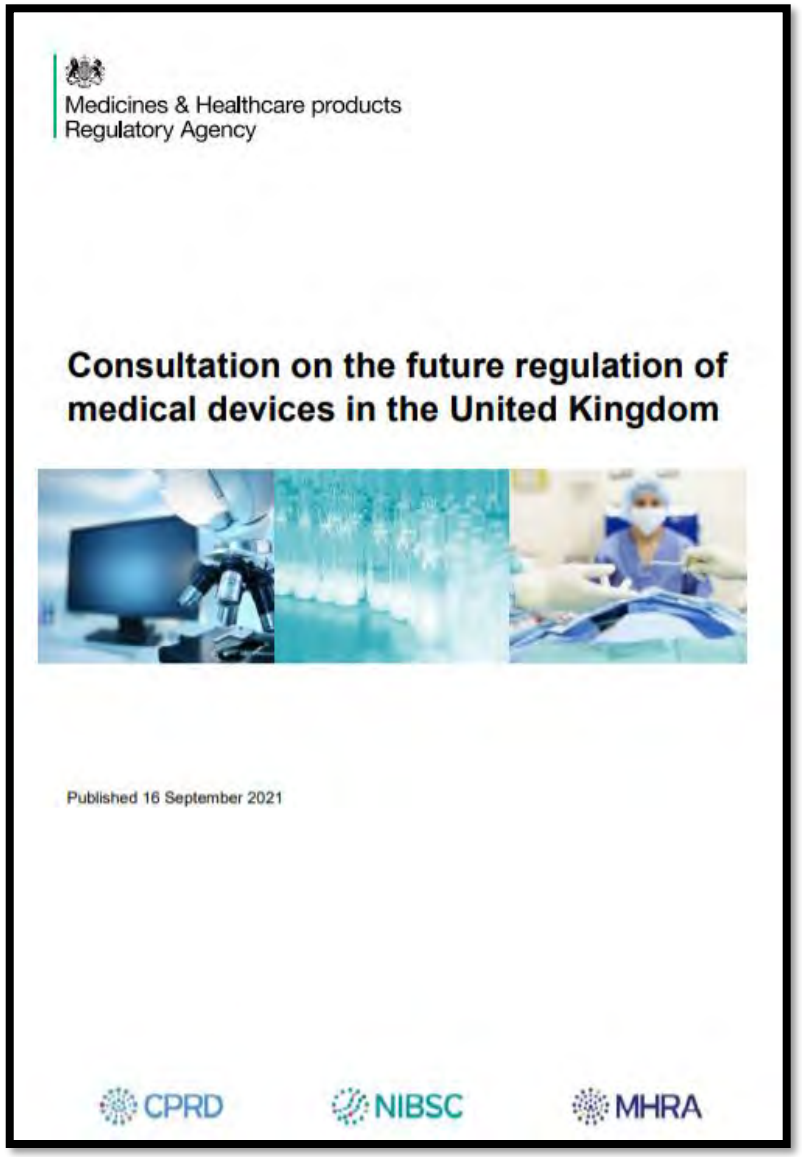
The Medicines and Healthcare products Regulatory Agency (MHRA) is inviting members of the public to provide their views on possible changes to the regulatory framework for medical devices in the United Kingdom (UK). We want to develop a future regime for medical devices which enables:

- Improved patient and public safety;
- Greater transparency of regulatory decision making and medical device information;
- Close alignment with international best practice, and;
- More flexible, responsive and proportionate regulation of medical devices.

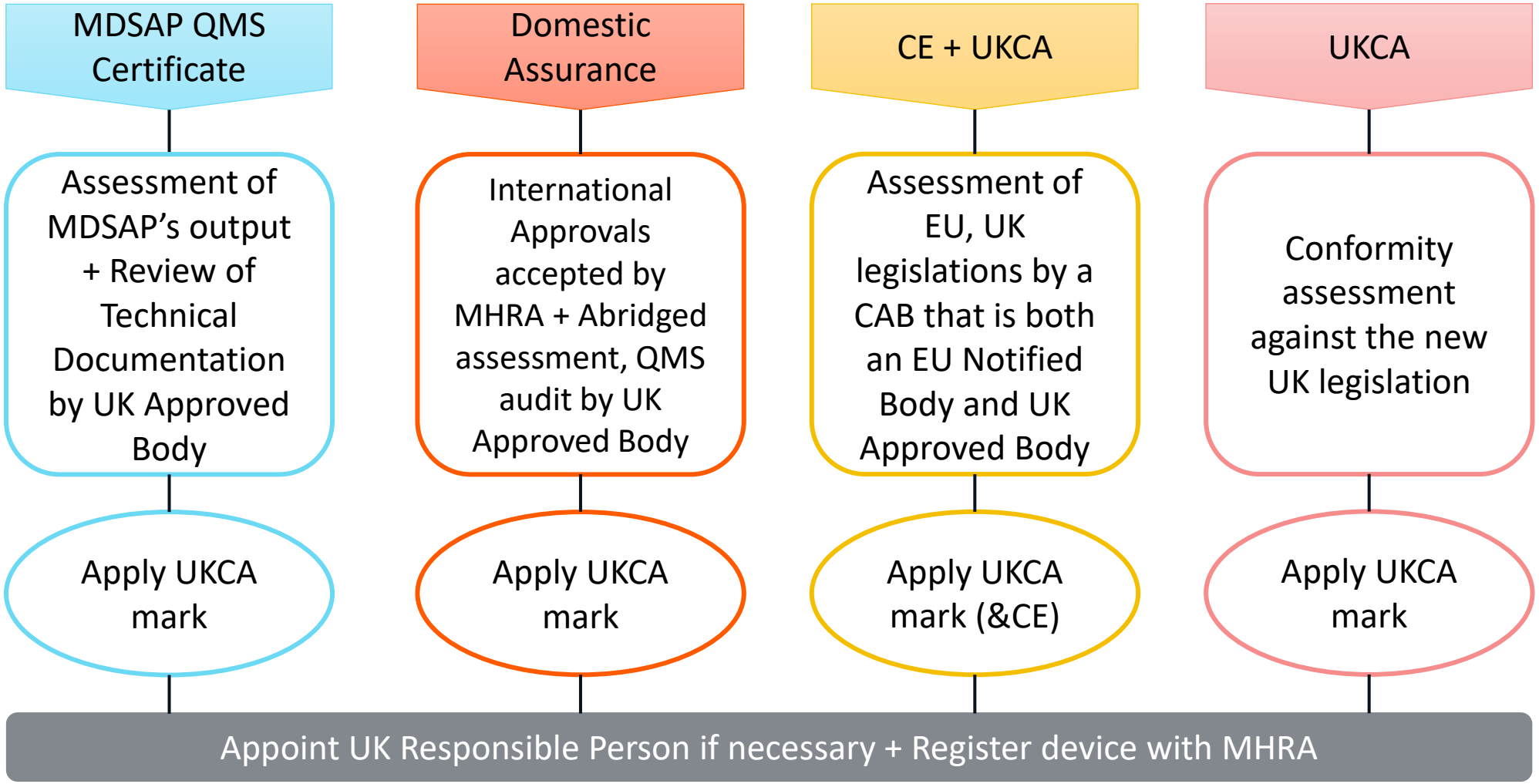


Consultation on future legislation

Chapter 1: Scope of the Regulations
Chapter 2: Classification
Chapter 3: Economic Operators
Chapter 4: Registration and UDI
Chapter 5: Approved Bodies
Chapter 6: Conformity Assessment
Chapter 7: Clinical Investigation / Performance Studies
Chapter 8: Post-market Surveillance, Vigilance, Market Surveillance
Chapter 9: In vitro Diagnostic Medical Devices
Chapter 10: Software as a Medical Device
Chapter 11: Implantable Devices
Chapter 12: Other Product-Specific Changes
Chapter 13: Environmental sustainability and public health impact
Chapter 14: Routes to market
Chapter 15: Transitional Arrangements
Chapter 16: Feedback
Chapter 17: Questions for members of the general public



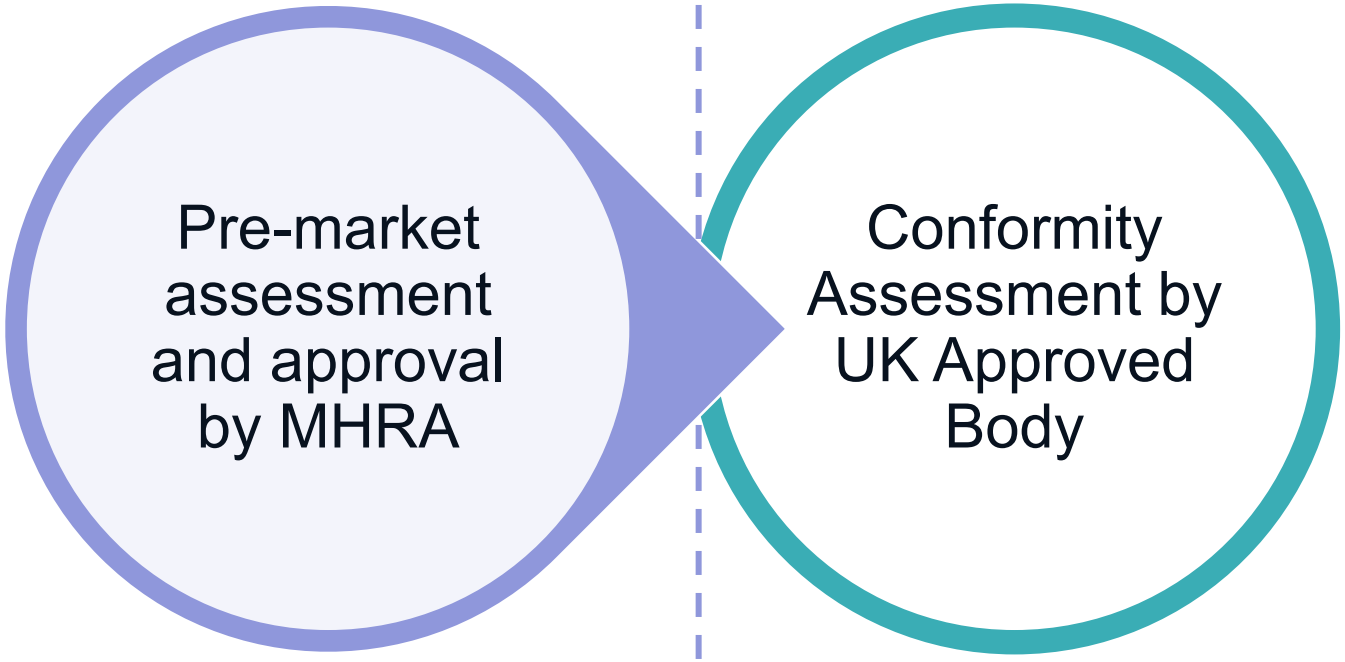
Chapter 14: Proposed Routes to Market



Chapter 14: Innovative Medtech- Alternative Pathway

Innovative Medtech Criteria

- Size of patient population – rare conditions / small patient groups
- Scale of innovation – “game changers”
- Size of manufacturer – targeting SMEs



Market access with approval limited to specific circumstances

No UKCA marking

UK CA

Poll

Will a UKCA certificate be valid beyond July 2023?

Yes

No

It depends

Proposed Transitional Arrangements

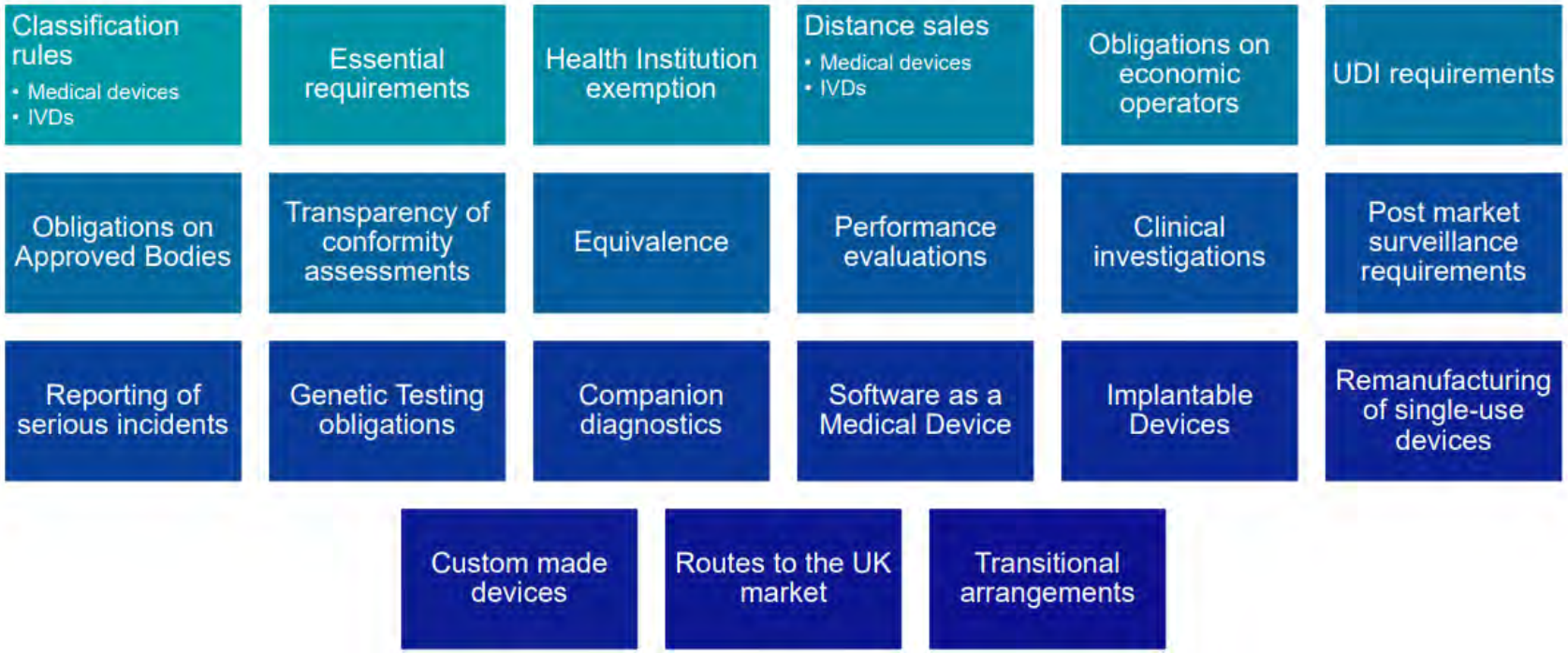
Devices placed on the market with a valid UKCA Certificate or Declaration of Conformity prior to 01 July 2023

- Can remain on the market until the expiry of the certificate/DoC or until a specified date whichever is earliest

Devices placed on the market with a valid CE certificate or Declaration of Conformity prior to 01 July 2023

- Can remain on the market until the expiry of the certificate/DoC or until a specified date whichever is earliest, but with a 'light touch' assessment against the UK legislation

Focus Groups



- **Approved Bodies**
- Clinical Rep
- Patient Groups
- Trade Associations
- Devolved Administrations

To provide an opportunity to help shape the guidance documents and other supporting materials that will accompany the new Medical Device Regulations

To provide an opportunity to raises issues that need to be covered by those guidance materials

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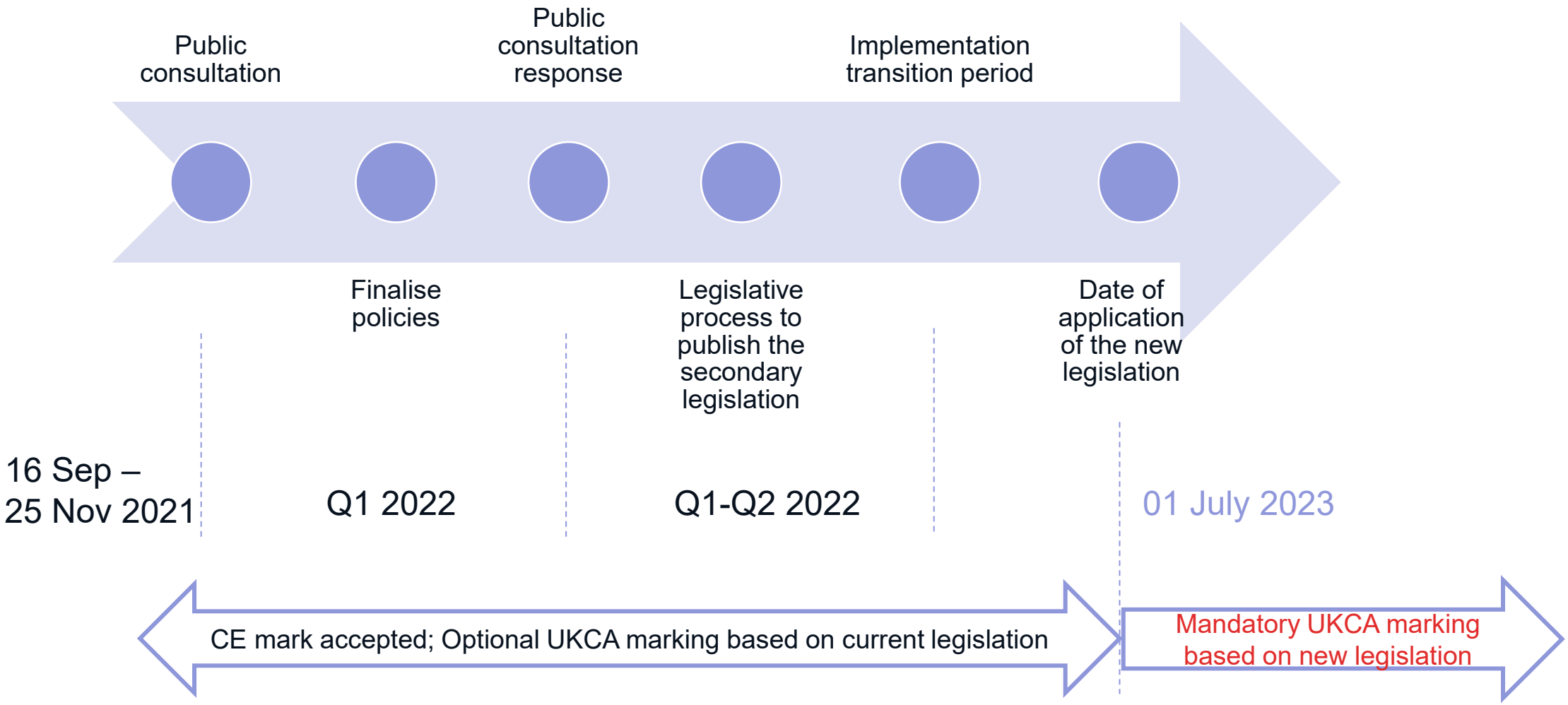
Current Timelines



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I have an EC certificate only, am I able to place devices on the GB market with a UKCA mark during the transition period?

Yes

No

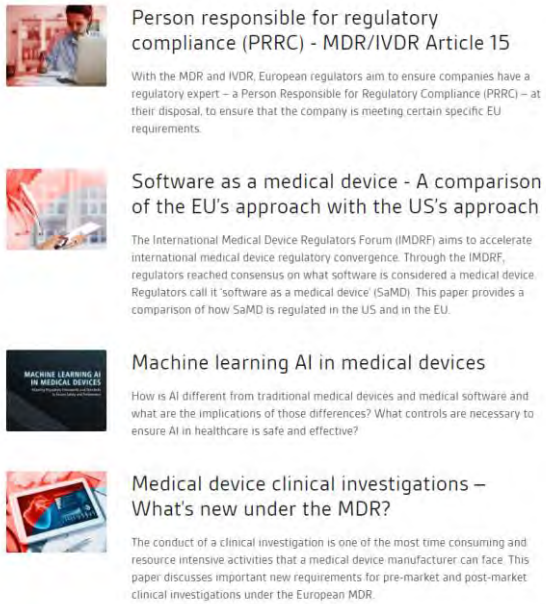
BSI Medical Devices – Use Our Resources

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

Brochures, Guides and Documents

Webinars

White Papers and Articles



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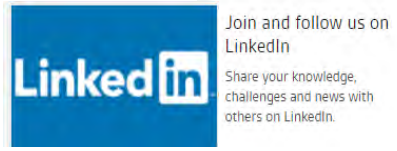

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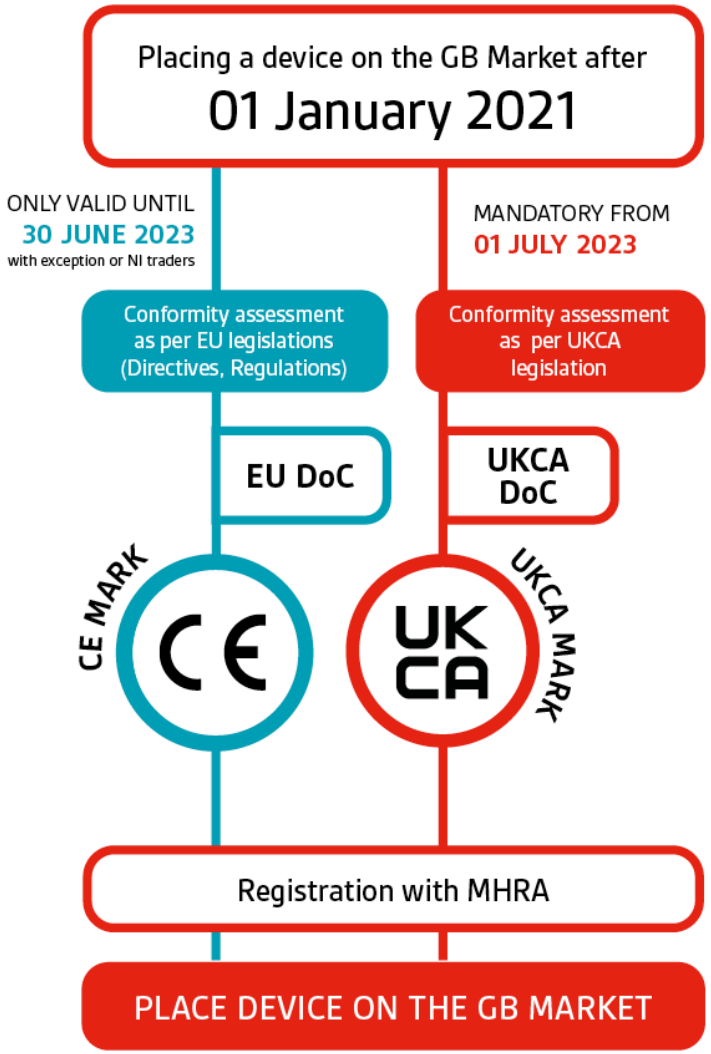
Closing Remarks



Thank you for listening