

Brexit: Impact on RPE

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By Royal Charter

bsi.

Brexit: Impact on the RPE

1. Brexit
2. Conformity assessment bodies
3. Impact on UK regulatory landscape
4. UKCA mark
5. Impact on RPE

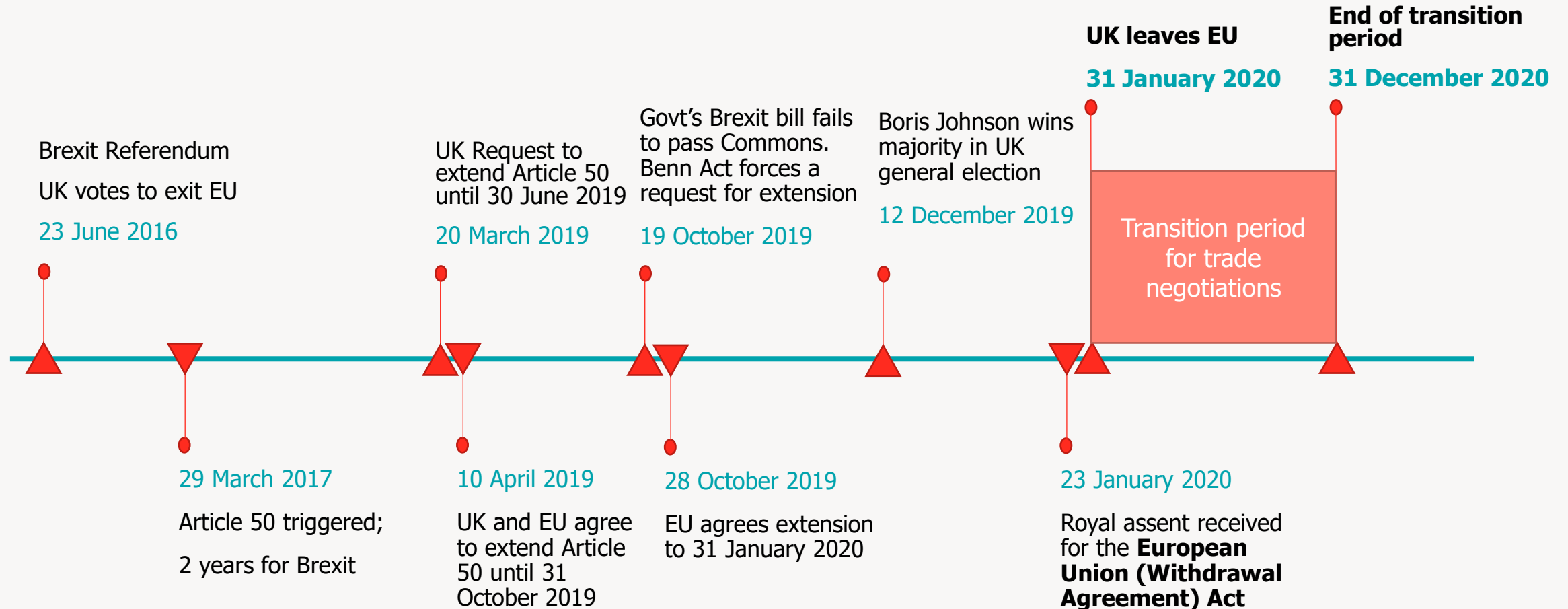
Speaker –

Graham Clements, Certification Manager PPE, BSI Assurance UK/The Netherlands



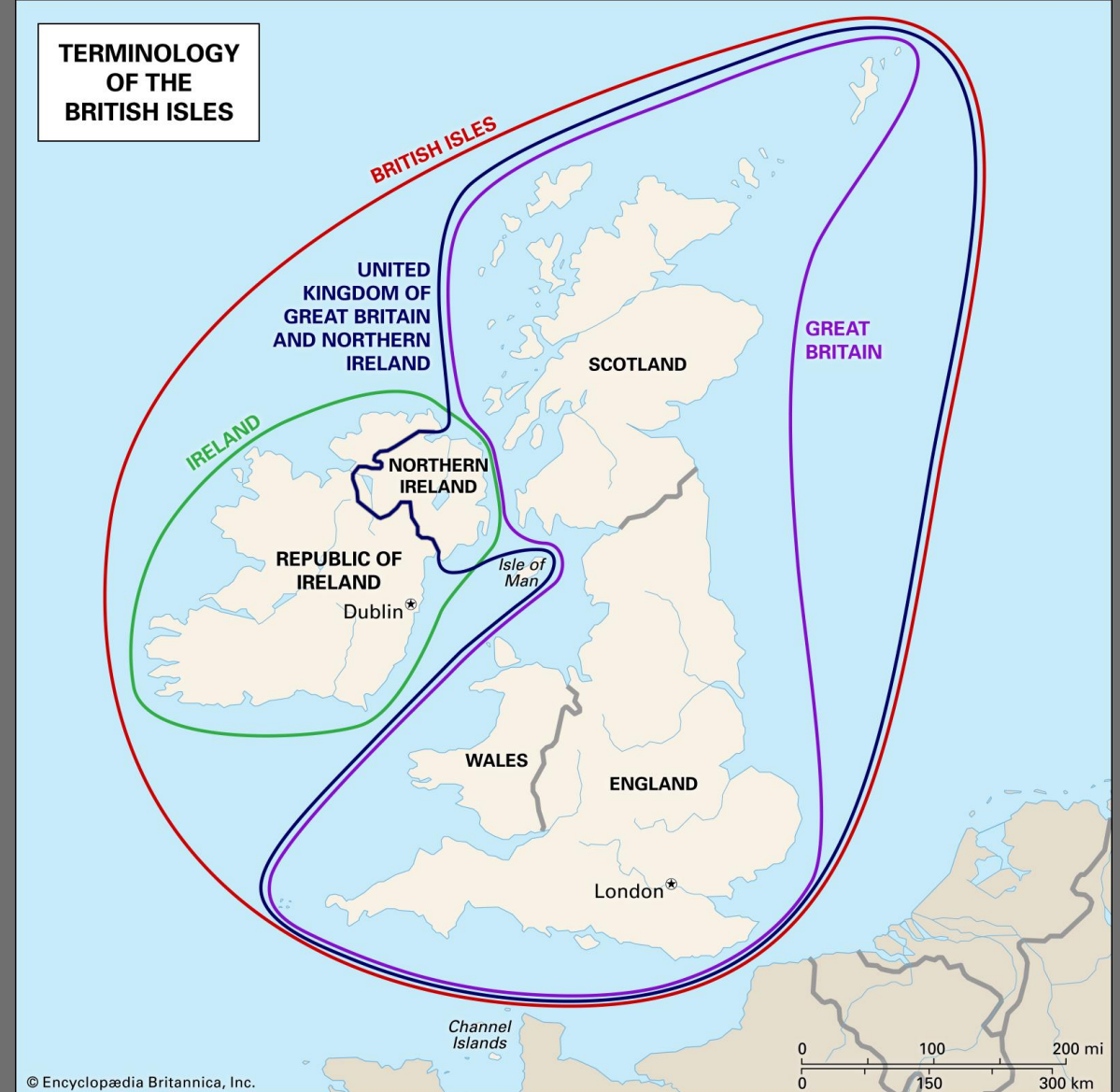
Brexit

Brexit Timeline - Key Milestones



Geography Lesson

- Regulatory zones:
 - Northern Ireland (NI)
 - Great Britain (GB)
 - United Kingdom (UK)



Source: Encyclopaedia Britannica

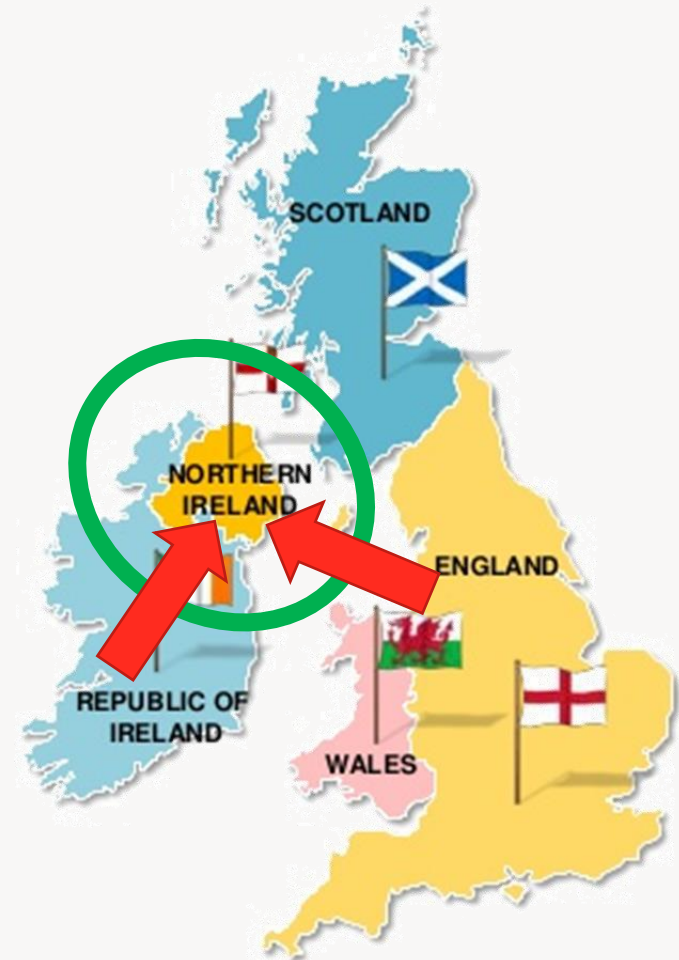
Northern Ireland – a unique challenge

- Northern Ireland Protocol and Anglo-Irish Agreement make the introduction of any hard border politically very difficult.
- Manufacturers in Northern Ireland have unfettered trade with ROI and rest of the UK



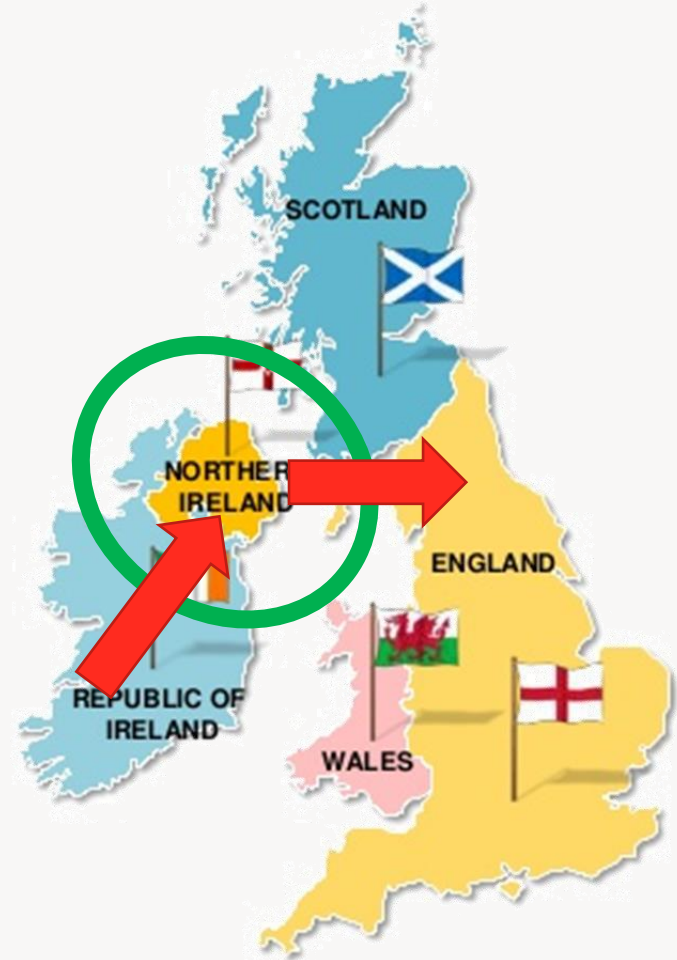
Importing goods into Northern Ireland

- Companies bringing goods into NI from GB or non-EU countries will become “**Importers**”.
- Most product-safety regulations impose duties on “Importers” to make checks to ensure that products do meet regulations
- For goods from the EU, companies will be “distributors”, with reduced responsibility



Importing & Distributing - Example

1. Goods of origin in the EU
2. NI Ireland business is distributor
3. But if goods then supplied on to GB the NI business becomes a UK importer
4. You cannot route goods through NI to avoid the UKCA regulations in force in GB



About Brexit

- CE Marking has applied to products supplied into the UK since the 1990's...
- The UK left the European Union on **31st January 2020**
- UK is in a transition period that will end on **31st December 2020**
- UKCA marking will come into force in Great British (GB) from **1st January 2021**
- CE marking will be recognized in GB until the end of 2021*
- From **1st January 2022**, only products with UKCA marking will be accepted*



UK CA

“UK Conformity Assessed” mark

Summary

- The UK left the EU on 31 January 2020 and the agreed transition period ended at the end of 2020
- Northern Ireland has special provisions
- Role of distributors and importers may change
- Transition deadlines

Conformity

Assessment Bodies

The key differences (for now)...

EU Directives &
Regulations



Many EU regulations require the use of an EU appointed “**Notified Body**” to perform product inspections and/or conduct factory quality inspections as part of the attestation process.

UK Regulations



UK regulations have the same requirement but this activity now must be performed by a UK-appointed “**Approved Body**” such as BSI

Who can offer conformity assessment services?



EU Directives & Regulations
for EU27 market access

Many EU regulations require the use of an EU appointed “**Notified Body**” to perform product inspections and/or conduct factory quality inspections as part of the attestation process.
BSI is a Notified body for CE marking (2797)



UK Regulations for UK
market access



UK regulations have the same requirement but now must be performed by a UK-appointed “**Approved Body**” such as BSI
BSI is an Approved Body for UKCA (0086)

About the requirements for conformity



EU Directives &
Regulations

- Low Voltage
- EMC Directive
- Gas Appliances
- Pressure Equipment
- Energy Related Products
- ROHS
- PPE
- Construction Products
- Marine Equipment
- ...Etc, etc

***The Product Safety and Metrology
etc. (Amendment etc.) (EU Exit)
Regulations 2019***



"The Great Repeal Act"



UK Regulations

Initially the UK and EU
requirements remain
identical from a technical
perspective...

UK Regulation Framework - Examples

EU Directives & Regulations	UK Regulations
Low Voltage Directive	Electrical Equipment (Safety) Regulations 2016
EMC Directive	Electromagnetic Compatibility Regulations 2016
Gas Appliances Regulation	Regulation 2016/426 on gas appliances as brought into UK law and amended
Radio Equipment Directive	Radio Equipment Regulations 2017
Pressure Equipment Directive	Pressure Equipment (Safety) Regulations 2016
Construction Products Regulation	Construction Products Regulations (Regulation (EU) 305/2011 as brought into UK law and amended)
PPE Regulation	Regulation 2016/425 on personal protective equipment as brought into UK law and amended
ROHS Directive	The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
See (https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain#legislation)	

NANDO – EU NOTIFIED BODIES



EU Directives &
Regulations

- Low Voltage
- EMC Directive
- Gas Appliances
- Pressure Equipment
- Energy Related Products
- ROHS
- PPE
- Construction Products
- Marine Equipment
- ...Etc, etc

NANDO Database



[https://ec.europa.eu/growth/to
ols-databases/nando/index.cfm](https://ec.europa.eu/growth/tools-databases/nando/index.cfm)

What is there?

- Conformity assessment bodies by:
- Legislation:
- Directives/Regulations
- Countries
- Specific Annexes
- Product types (scope)

UK MARKET OF CONFORMITY ASSESSMENT BODIES



UK Regulations (mirrored)

- Low Voltage
- EMC Directive
- Gas Appliances
- Pressure Equipment
- Energy Related Products
- ROHS
- PPE
- Construction Products
- Marine Equipment
- ...Etc, etc

UKMCAB database



<https://www.gov.uk/uk-market-conformity-assessment-bodies>

What is there?

- Conformity assessment bodies by:
- Body type – Approved Body
- Locations
- Legislation

Summary

- All UK Notified Bodies became UK Approved Bodies from 1 January 2021
- For the EU we have Notified Bodies and for the UK we have Approved Bodies
- Notified Bodies are listed on NANDO and Approved Bodies are listed on UKMCAB
- Existing EU legislation and scopes have been mirrored for Approved Bodies
- Former UK Notified Bodies may have an EU Notified Body within the international structure of their organisation



Impact on UK regulatory landscape

Divergence...

On 1 January 2021

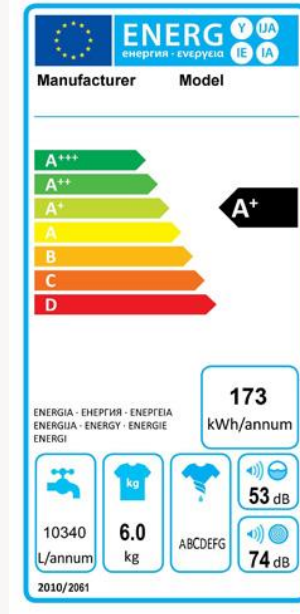
The UK and EU
requirements were largely
identical from a technical
perspective...



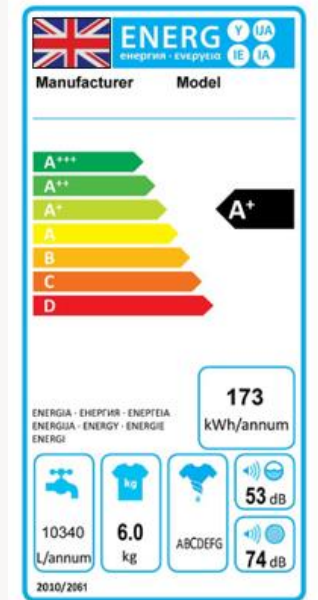
Divergence

- Most technical rules are contained within **standards**, not Regulations.
- UK remains committed to membership of CEN, CENELEC and ISO
- UK is likely to continue to use European standards and adopted ISO standards for most products
- Divergence will be small in short term...

EU Energy Label



UK Energy Label



Role of Standards... UKCA Marking

- UK regulations recognize the importance of standards in the same way
- Compliance with appropriate standards gives “presumption of conformity” under most regulations
- Compliance with appropriate standards may be mandatory for some regulations (e.g.: Construction Products)
- Appropriate standards are called “**Designated Standards**” in the UK
- These are nearly identical to the EU lists, but can be expected to diverge
- Will be EN standards, but could be ISO, IEC, BS, etc.
- <https://www.gov.uk/guidance/designated-standards>

What might happen...over time...

UK
CA

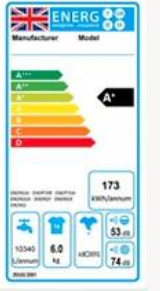
1st January 2021

The UK and EU requirements remain **identical** from a technical perspective...

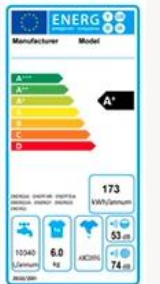
Possible divergence over time

The UK and EU remain free to amend their regulations or introduce new regulations to suit their own needs. These may or may not be harmonized...

CE



Example



Summary

- The UK will continue to adopt EN and ISO standards
- EU legislation is largely mirrored in the UK
- ‘Designated’ standards have been listed
- Technical requirements are the same but may diverge over time

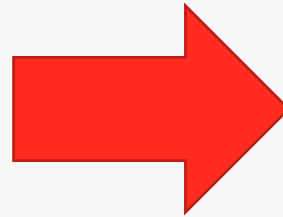


UKCA Mark

Overview



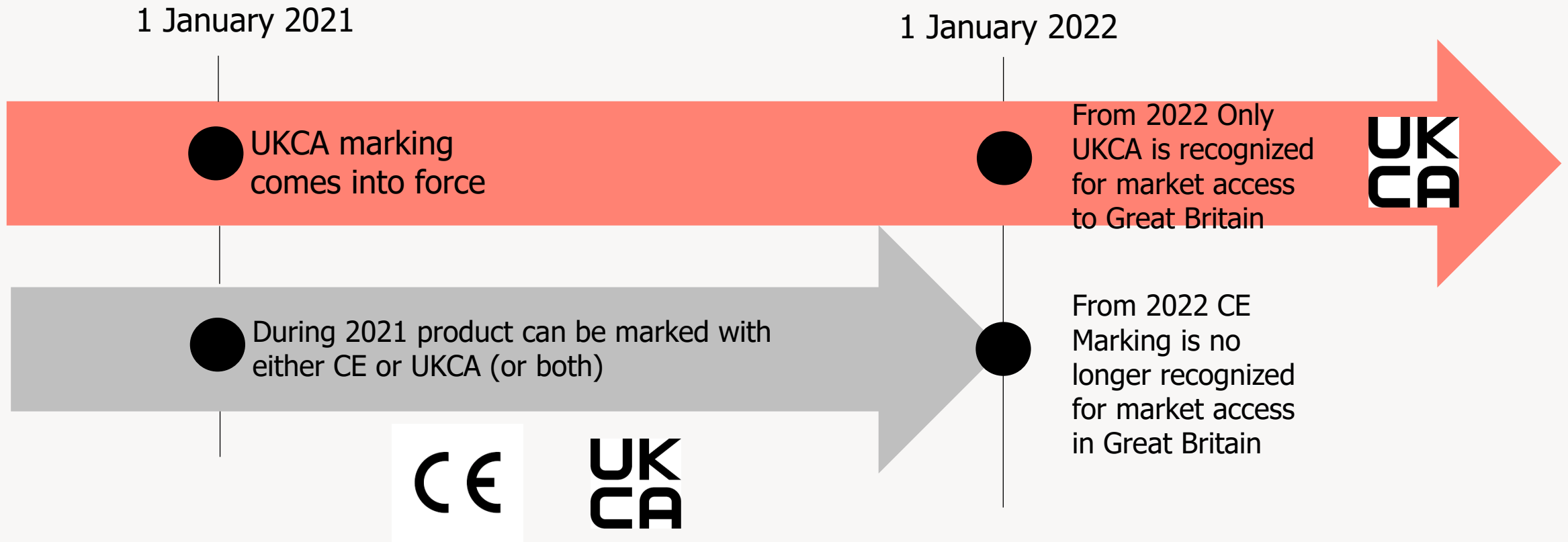
Affixing the CE Mark to a product declares compliance with all relevant EU Regulations



Affixing the UKCA Mark to a product declares compliance with all relevant **UK** Regulations

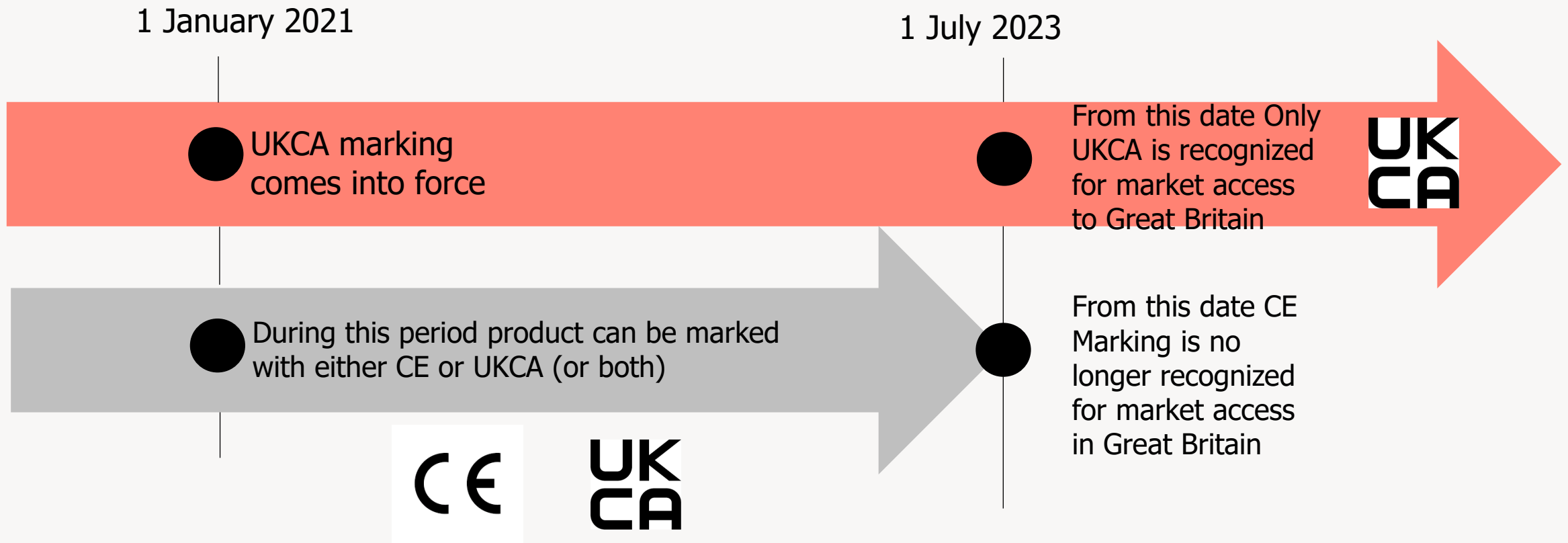
UKCA Deadline

For majority products



UKCA Deadline

Medical Devices and In-vitro Diagnostics Devices



Who is UKCA marking for?

Manufacturers of products covered by Directives or Regulations

For example the following types of products:

- Construction Products
- Personal Protective Equipment
- Gas Appliances
- Boiler Efficiency
- Pressure Equipment
- Lifts
- Marine Equipment
- Measuring Instruments
- Radio Equipment
- Medical Devices
- In-Vitro Diagnostics Devices



Note - many directives that are self-declaration will be largely unaffected as they will not require the services of an Approved Body, e.g. Toys, LVD

The UKCA Mark

The UKCA Mark logo consists of the letters 'UK' stacked above 'CA' in a bold, black, sans-serif font. The letters are thick and blocky, with the 'U' and 'C' having rounded bottoms and the 'K' and 'A' having sharp, angular tops.

- “UK Conformity Assessed”
- Can be affixed from 1 January 2021
- Must be affixed to most products from 1 January 2022
- Operates in broadly the same manner as CE marking

Format of UKCA mark



- For Regulations where no **Approved Body** is required, for example
 - Electrical equipment
 - ROHS
 - EMC
 - Toys
 - Some machinery & pressure equipment
 - Some construction products
- Operates by self declaration as with CE Marking

Format of UKCA mark



- For Regulations where an **Approved Body** is required, for example
 - Gas Appliances
 - Most construction products
 - Radio Equipment
 - Personal Protective Equipment
 - Dangerous Machines (Annex IV)
 - Most pressure equipment
- UK Approved Body number must be affixed alongside the UKCA Mark

Markings can be combined...

UKCA Mark may be combined with the CE Mark if needed for both EU & UK markets



BSI Netherlands "Notified Body" number

BSI UK "Approved Body" number

The key differences (for now)...

EU Directives &
Regulations



Manufacturer must draw up an
“**EU Declaration of Conformity**”
for their product



UK Regulations



Manufacturer must draw up a
“**UK Declaration of Conformity**”
for their product

PLACING GOODS ON THE NI MARKET



- The Ireland/Northern Ireland Protocol is now in force.
- Goods placed on the market in NI will need to meet relevant EU rules.
- The CE marking will be accompanied by the UKNI marking when assessed by a UK Approved body.
- The UKNI is never applied on its own. It always accompanies the relevant EU conformity
- The UKCA marking alone will not be valid for the NI market.

Which mark should I use...?

- Products supplied in Northern Ireland must comply with the relevant **EU regulations**.

Notified Body Used	Mark to affix
None needed	CE
EU-27 Notified Body	CE 2797 (EU NB number)
UK Notified Body	CE UK NI 0086 (UK NB number)



NB: Most UK Notified Bodies were appointed both as Approved Bodies (GB) and Notified Bodies for Northern Ireland

Summary

- UKCA mark has been developed to provide market access to Great Britain
- Organizations that used a non-UK Notified Body could lose access to the UK market
- Compliance in GB is demonstrated via the UKCA Mark
- The UKCA marking alone will not be valid for the NI market
- Compliance in NI is demonstrated via CE Mark, or the CE UKNI mark if you used a UK Notified and Approved Body
- Northern Ireland businesses can place qualifying products onto the whole UK market using CE mark or CE UKNI mark

UK
CA

UK
NI



Impact on RPE

Case Study - UKCA marking for PPE

PPER modules

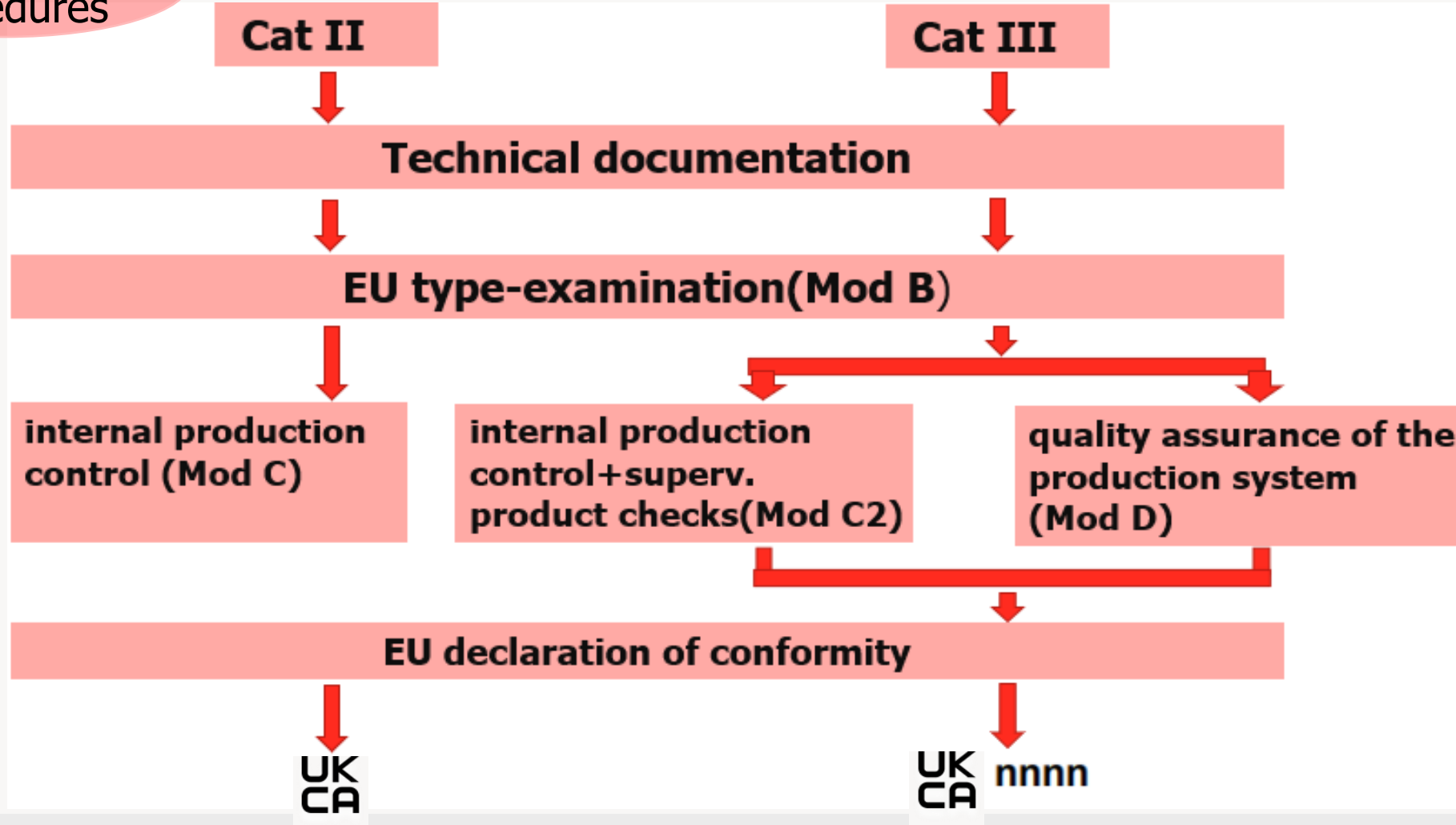
UK
CA

PPE Category	Activity	PPE Regulation (EU)2016/425
Cat I	Place onto market	Module A(Annex IV)
Cat II Intermediate PPE and Cat III Complex PPE	Initial product approval	Module B(Annex V) EU Type Examination Module C(Annex VI)
Cat III Complex PPE only	On-going surveillance (testing/factory auditing)	Module C2(Annex VII)/ Module D(Annex VIII)

Case Study - UKCA marking for PPE

UK
CA

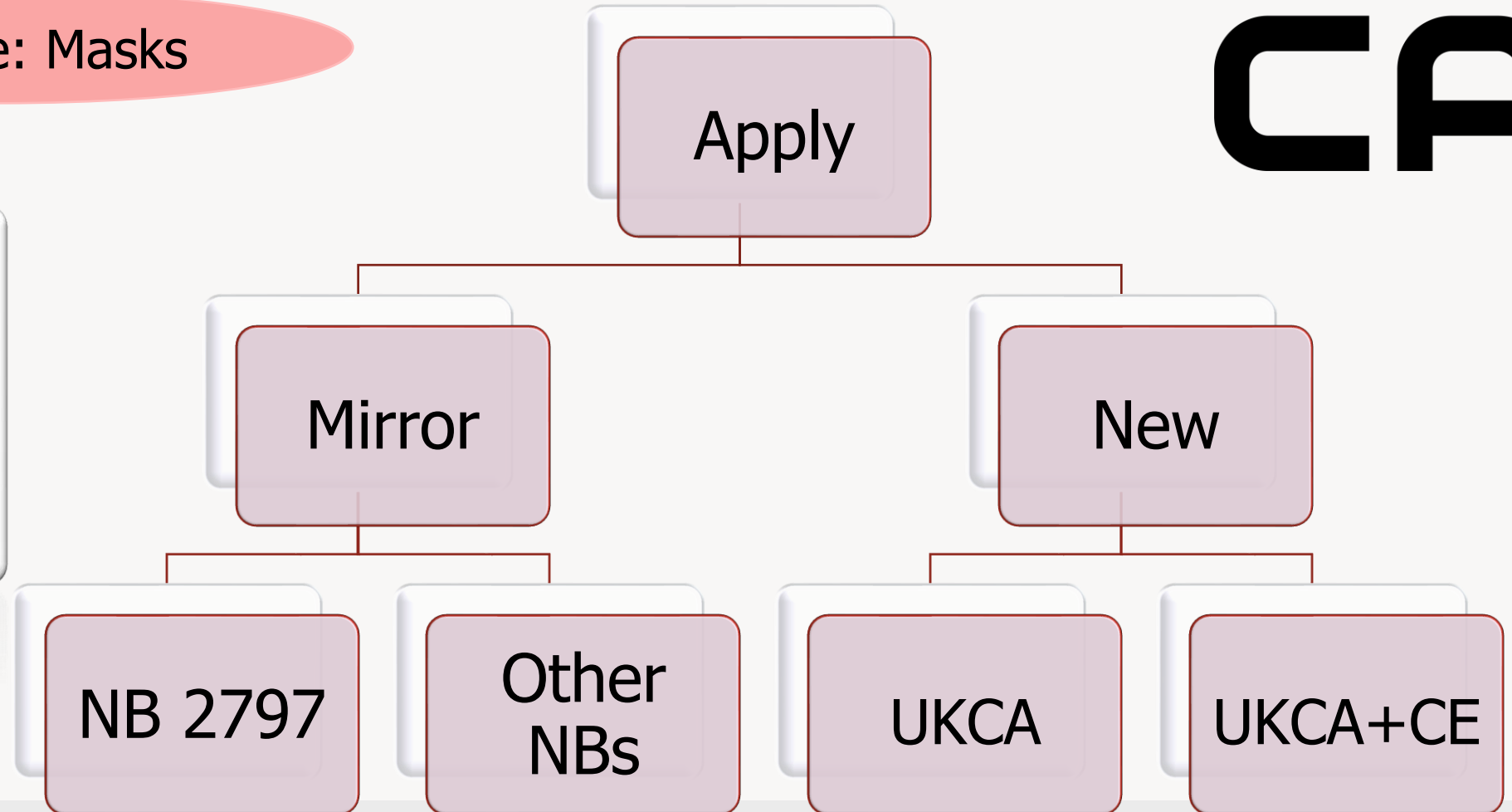
PPER
Procedures



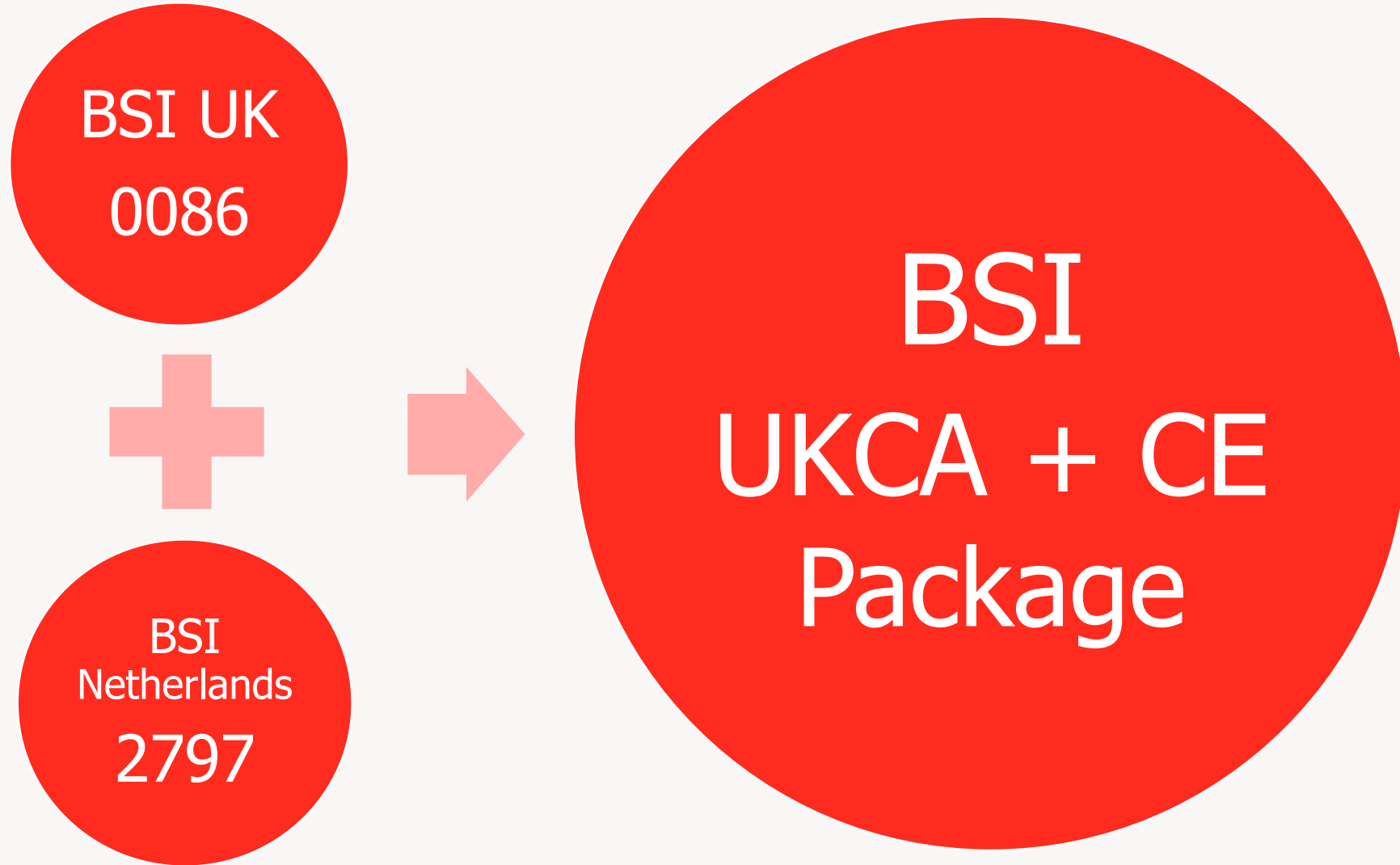
Case Study - UKCA marking for PPE

UK
CA

Example: Masks



BSI – CE+UKCA



Changes on Technical Document Requirements

- UKCA Marking on Product, packaging, etc.
- User Information references to UKCA and Approved Body
- UK Authorized representative, to be shown on DoC
- Relevant UK Legislation instead of EU should be listed on DoC
- Detail of UK Approved Body should be listed on DoC

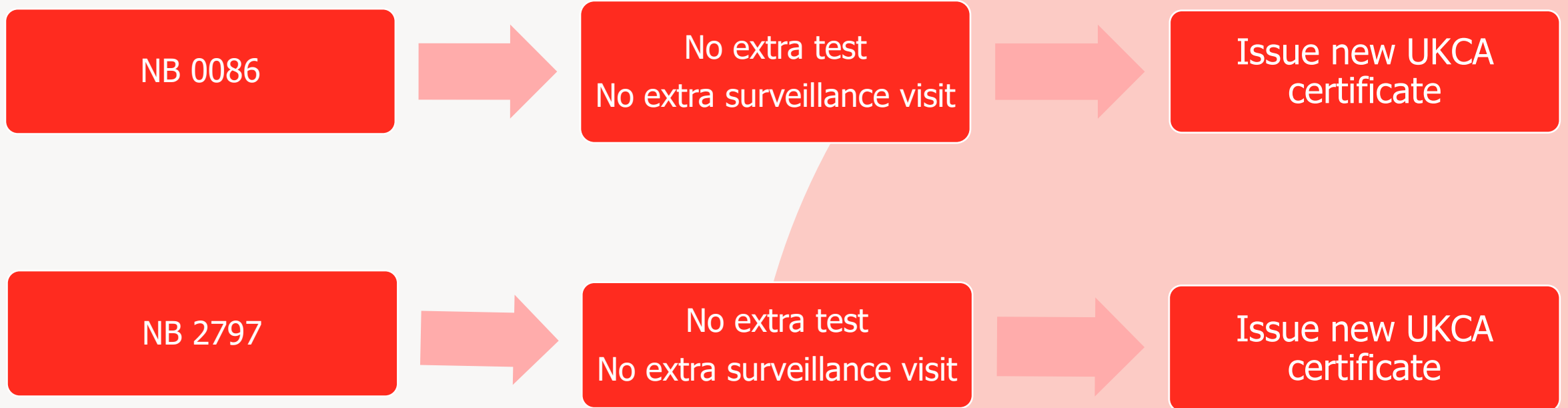
Refer to:

<https://www.gov.uk/guidance/using-the-ukca-marking#how-to-use-the-ukca-marking>

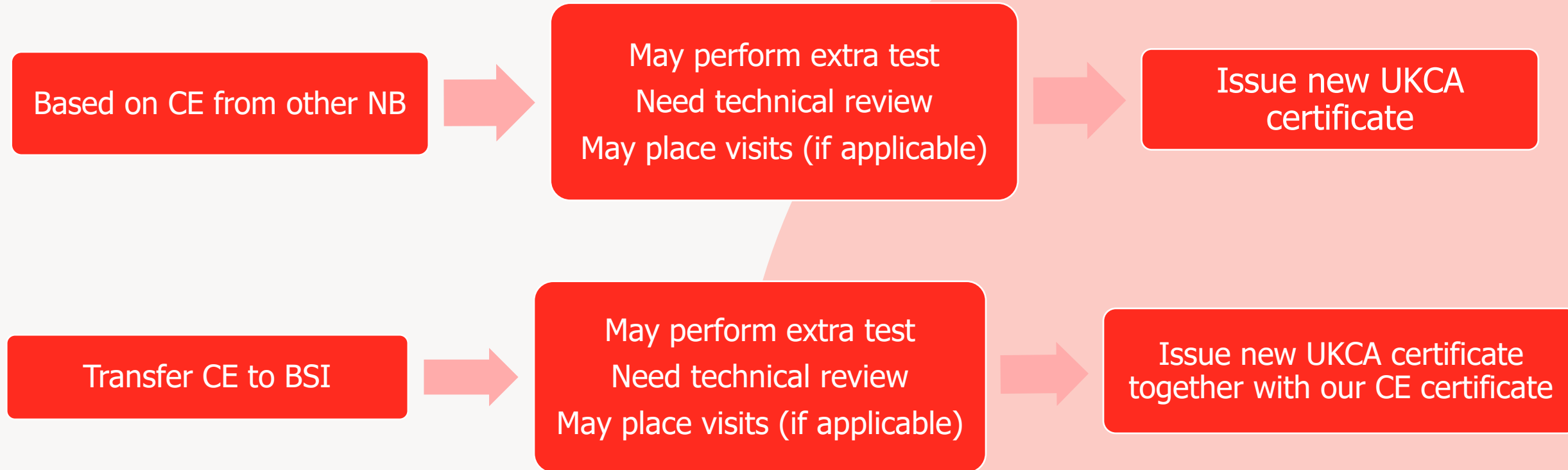
At least
5mm

The image shows the UKCA marking logo, which consists of the letters 'UK' stacked above 'CA' in a bold, sans-serif font. A red double-headed vertical arrow is positioned to the left of the logo, indicating a minimum height of 5mm for the marking.

UKCA Application – Existing BSI Clients with CE Marking



UKCA Application – non-BSI clients holding CE Certificates



UKCA Application – non-BSI clients producing CE self-declared items



Designated Standards... RPE

- Compliance with designated standards gives “presumption of conformity”
- Annex I gives clear variants of currently designated standards e.g.:
 - EN 943-1:2015 and EN 943-1:2015+A1:2019
 - EN 14594:2005 and EN 14594:2018
- Annex II gives clear dates when presumption of conformity removed
- Standards where presumption of conformity will be removed e.g.:
 - EN 943-1:2015, 19 November 2021
 - EN 14594:2005, 19 November 2021
- May be important for mirroring

The End

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