TÜV Rheinland UK Online-Seminar
IMPACT OF BREXIT

UKCA and UK(NI) Marks
What to do, How to do it, When to do it!

Justin Morgan, Principal Engineer TÜV Rheinland UK

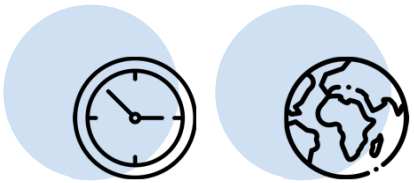
Nov 18th 2020 – 5 pm (GMT)

TÜVRheinland®
Precisely Right.

Good morning and welcome to our Online Seminar: IMPACT OF BREXIT

UKCA and UK(NI) Marks

What to do, How to do it, When to do it!



We will start in a few minutes ! Attention Waiting time

We would like to ensure no one will miss valuable information
and give everyone the chance to dial in
as we have participants from different time zones.

THANK YOU FOR YOUR KIND PATIENCE !

TÜVRheinland®
Precisely Right.

Agenda UKCA and UK(NI) Mark

Our Topics for today

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

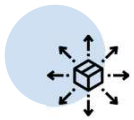
1. Welcome and Technical support

Some How To‘s for our online seminar attendees

Duration of our online seminar. 45 min + Q&A

If you have **audio issues** connecting by PC, please, try to join and dial in via phone
(you can find your number based on your location here: https://tuv.zoom.us/u/kdtZWpwtvo
eventually change your browser from Firefox to Chrome or other

Please type your questions into the Q&A panel - we will answer you at the end of the presentation or include yours into an FAQ document if we are running out of time



We will share the presented information with you for download by email after our online seminars

!

IMPORTANT NOTICE. Our online seminar operated via Zoom includes a feature that allows audio and any documents and other materials exchanged or viewed during the session to be recorded. By joining this session, you automatically consent to our recordings.
If you do not consent to the recording, feel free to discuss your concerns with us prior to the start of recording.

TÜVRheinland®
Precisely Right.

Today‘s speaker

Justin Morgan

Principal Engineer (TÜV Rheinland UK)

Speaker Introduction

- Our expert Justin Morgan is a specialist in product certification and movement of products
- During his tenure at TUV Rheinland UK, he has been able to gain great expertise and a tight network to stay informed on the most critical parts of BREXIT that affect our industries.

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

2. The Marks and Terms

UKCA and UK(NI) Mark

UKCA (UNITED KINGDOM CONF0RMITY ASSESSMENT) MARKING

- New UK product marking
- Will be used for goods being placed on the market in Great Britain (England, Wales, Scotland)
- Covers most goods which previously required the CE marking

Logo solid color black

Logo white negative

Note:
When placed on product the UKCA/ UK(NI) mark must be ***at least 5 mm in height*** (unless relevant legislation states otherwise)

UK(NI) MARK (FOR NORTHERN IRELAND ONLY)

- Can be placed next to a CE mark
- To show the product is suitable for Northern Ireland
  - But cannot be supplied to the rest of the EU

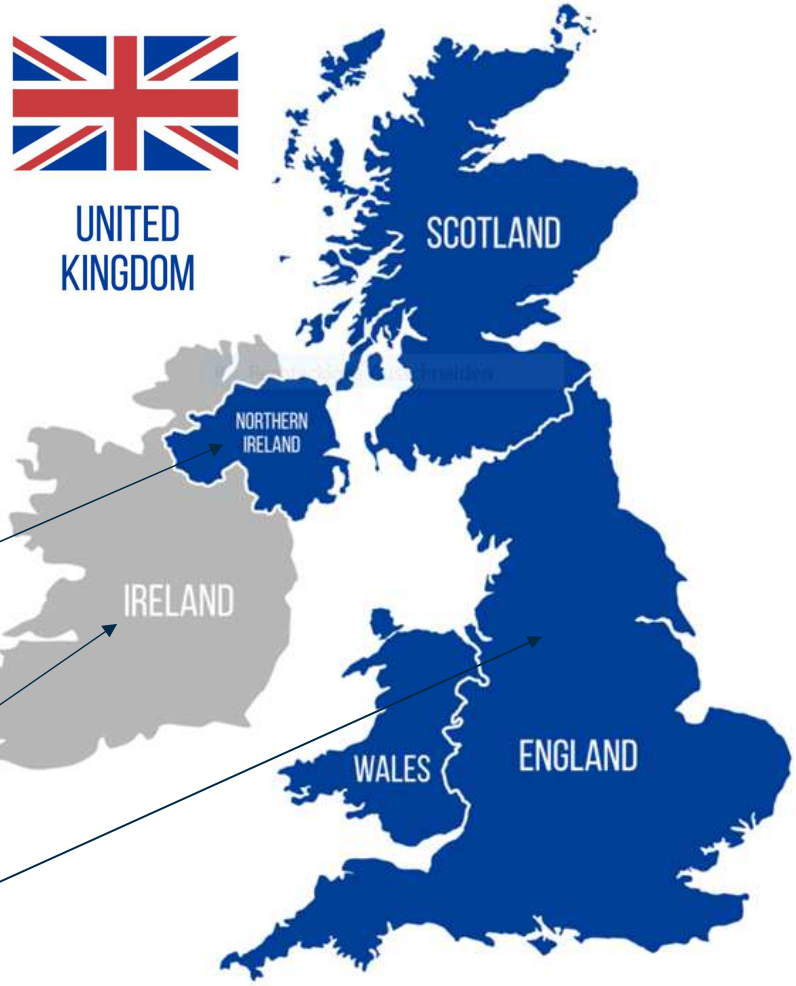
TÜVRheinland®
Precisely Right.

2. The Marks and Terms

UKCA and UK(NI) Mark

Why special rules for Northern Ireland?

- The Belfast Agreement (also know as the Good Friday Agreement) was agreed in 1998 in order to bring peace and stability to the Republic of Ireland (ROI), Northern Ireland (NI) and Great Britain (GB).
- Due to the Belfast Agreement a hard border between NI and ROI is not feasible.
- This means there is no hard border between NI and the EU (as ROI remains part of the EU) so the special rules for Northern Ireland were created.



- Northern Ireland
- Republic of Ireland (Part of the EU)
- Great Britain (England, Scotland, Wales)

TÜVRheinland®
Precisely Right.

3. The Marks and Terms

Overview Terms

Notified Body (NoBo)	A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. UK notified bodies will no longer be recognised by the EU from 01/01/2021 (in most cases these will automatically become a UK Approved body).
UK Approved Body	An organisation designated by the UK to assess conformity of certain products before being placed on the UK market.
DoC	A DoC or Declaration of Conformity is a manufacturers declaration stating that their product meets all the requirements for a product to be placed on the market. (A separate DoC is required by both for the EU and UK).

Agenda UKCA and UK(NI) Mark

4. Legislations covered under UKCA

EU Directives/ Legislation vs UK Legislation

EU legislation	UK legislation
Toy Safety - Directive 2009/48/EC	Toys (Safety) Regulations 2011
Recreational craft and personal watercraft - Directive 2013/53/EU	Recreational Craft Regulations 2017
Simple Pressure Vessels - Directive 2014/29/EU	Simple Pressure Vessels (Safety) Regulations 2016
Electromagnetic Compatibility - Directive 2014/30/EU	Electromagnetic Compatibility Regulations 2016
Low Voltage Directive 2014/35	Electrical Equipment (Safety) Regulations 2016
Non-automatic Weighing Instruments - Directive 2014/31/EU	Non-automatic Weighing Instruments Regulations 2016
Measuring Instruments - Directive 2014/32/EU	Measuring Instruments Regulations 2016
Lifts - Directive 2014/33/EU	Lifts Regulations 2016
ATEX - Directive 2014/34/EU	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016
Radio equipment - Directive 2014/53/EU	Radio Equipment Regulations 2017
Pressure equipment - Directive 2014/68/EU	Pressure Equipment (Safety) Regulations 2016
Personal protective equipment - Regulation (EU) 2016/425	Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended)
Gas appliances - Regulation (EU) 2016/426	Gas Appliances (Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019)
Machinery Directive 2006/42/EC	Supply of Machinery (Safety) Regulations 2008
Outdoor Noise Directive 2000/14/EC	Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001
Directive 92/42/EEC hot-water boilers AND Ecodesign Directive 2009/125/EC	The Ecodesign for Energy-Related Products and Energy Information (Amendment) (EU Exit) Regulations 2019
Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) - Directive 2002/95/EC	The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

4. Legislations covered under UKCA

EU Directives/ Legislation vs UK Legislation

- Latest UK legislation can be viewed at www.legislation.gov.uk
- Some of the UK legislations are amended by other legislation as mentioned in 'The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019' https://www.legislation.gov.uk/uksi/2019/696/made

TÜVRheinland®
Precisely Right.

4. Legislations covered under UKCA

List Product Types covered by UKCA

Product Types		
Toys Safety	Recreational craft and personal watercraft	Electronmagnetic compatibility
Personal protecitve equipment	Machinery	Radio Equipment
Gas Appliances	Lifts	Ecodesign
Low voltage electrical equipment	Pressure Equipment	Aerosols
Non-automatic weighing instruments	Simple pressure vessels	Outdoor Noise
Measuring instruments	ATEX	Restriction of hazardous substances

Products covered by UKCA

with special rules

- Medical Devices
- Construction Products
- Rail Interoperability
- Civil Explosives

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

5. Origin, Destination and Requirements

Movement of Products: Destination: ROW to UK

< 1st Jan 2021

Up until this date there is no change from current requirements

CE MARK ACCEPTED

In most cases there is no change in requirement and CE will be accepted

CE MARK ACCEPTED

1st Jan 2021 to 1st Jan 2022

EXCEPTION A

CE will only be accepted where the UK and EU rules align (whch they currently do)

- E.g. if the EU changes its rules regarding CE and you have based your CE marks on these rules that no longer align with the UK then a UKCA mark would be required*

EXCEPTION B

- If your product required a third party conformity assessment and it was carried out by a UK conformity assessment body (and has not since then been transferred to an EU conformity assessment body) then a UKCA mark will be required*

1st Jan 2022 – 1st Jan 2023

UKCA MARK DOCUMENTS

UKCA is mandatory for all products within its scope.

However, UKCA marking **may** be placed on the product or accompanying document for most products

- Product categories with special rules **must** have the UKCA mark on the product

UKCA MARK PRODUCT

> 1st Jan 2023

UKCA mark is mandatory and must be placed on the product**

Does not apply to Products with **Special Rules:**
Medical Devices
Rail Interoperability
Construction Products
Civil explosives

* On product or accompanying documentation

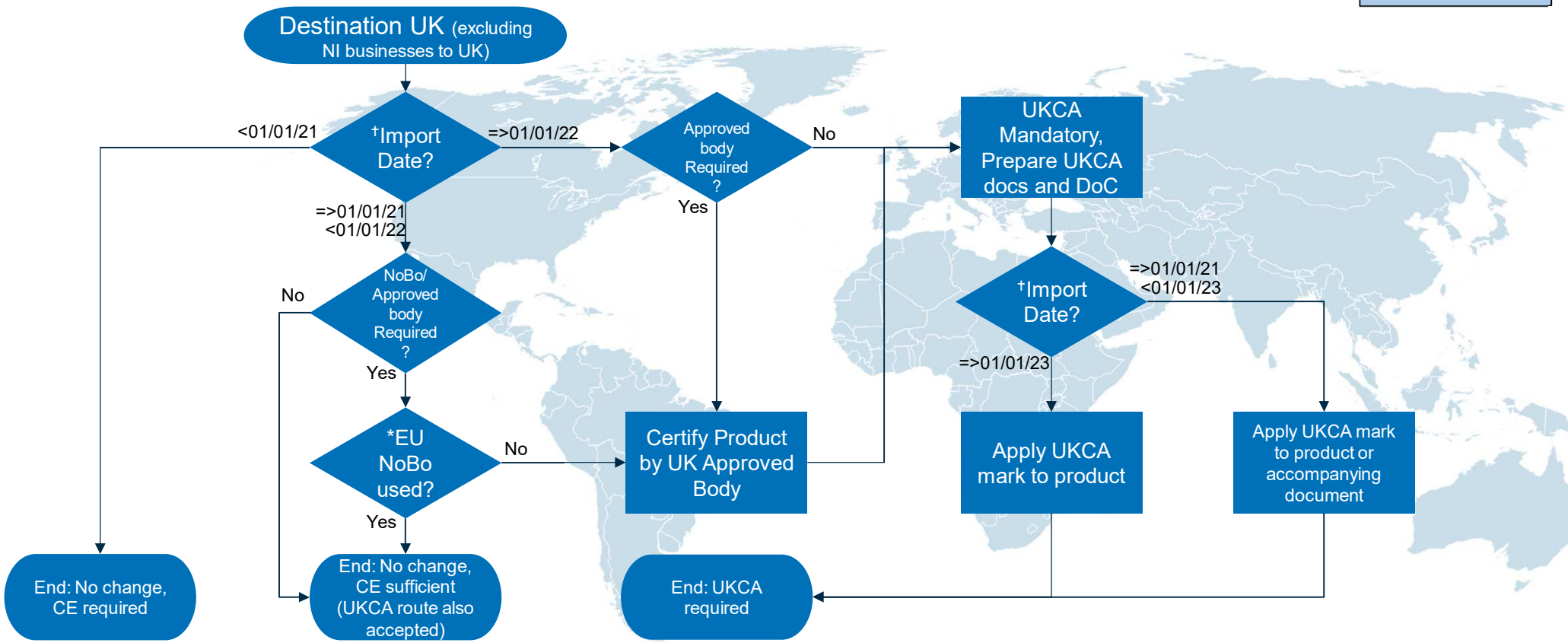
* *Some exceptions do exist but very few

Note: Northern Ireland has different requirements.

5. Origin, Destination and Requirements

Movement of Products: Destination ROW to UK

Does not apply to Products with **Special Rules:**
Medical Devices
Rail Interoperability
Construction Products
Civil explosives



* UK NoBo status will be withdrawn from 01/01/21, they will then become a UK Approved Body.

†Or date placed on market if product is already in UK.

TÜVRheinland®
Precisely Right.

5. Origin, Destination and Requirements

Movement of Products: NI to GB, GB to NI, ROW to NI, NI to EU

Does not apply to Products with **Special Rules:**
Medical Devices
Rail Interoperability
Construction Products
Civil explosives

< 1st Jan 2021

Up until this date there is no change from current requirements

Present to 2025

No change in requirement from current requirements

- 4 years after the transition period ends the Northern Ireland elected institutions may vote on the protocols alignment provisions.
- **CE required.**

GB to NI

> 1st Jan 2021

CE Mark is required

(UKCA is not valid for Northern Ireland)

- if the product required a third-party conformity assessment body and it was carried out by a UK notified body then an additional UK(NI) mark must be added alongside the CE mark (this means it is only suitbale for Northern Ireland and not for the whole of the EU)
- If an EU notified body was used then no UK(NI) mark is required

NI to GB

Present to 2025

- No change in requirements from current requirements for Northern Irish businesses.
- 4 Years after the transition period ends the Northern Ireland elected instituions may vote on the protocols alignment provisions.
- CE is acceptable for export to UK from Northern Irish businesses (registered headquaters must be in NI or GB)

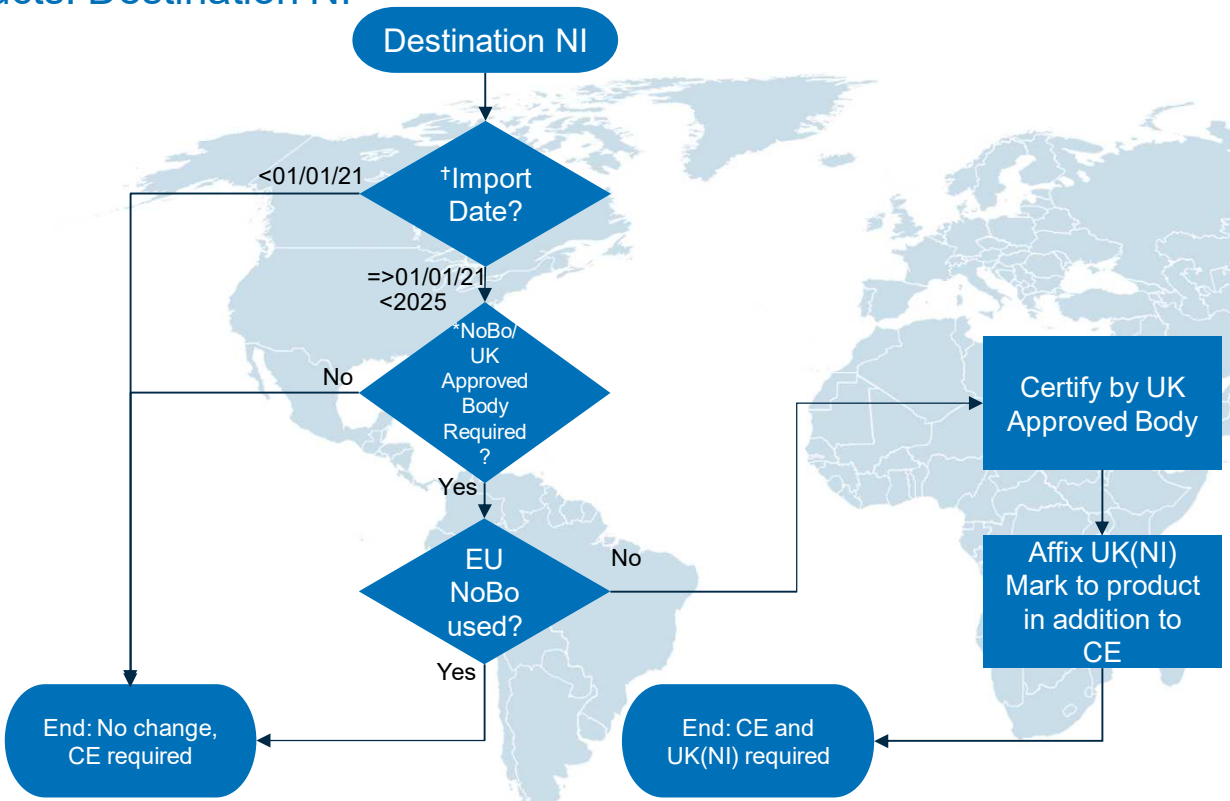
ROW to NI + NI to EU

Note:
*Products bearing the CE mark **and** UK(NI) mark cannot be placed on the market in the rest of the EU.*

5. Origin, Destination and Requirements

Movement of Products: Destination NI

Does not apply to Products with **Special Rules:**
Medical Devices
Rail Interoperability
Construction Products
Civil explosives



* UK NoBo status will be withdrawn from 01/01/21, they will then become a UK Approved Body.

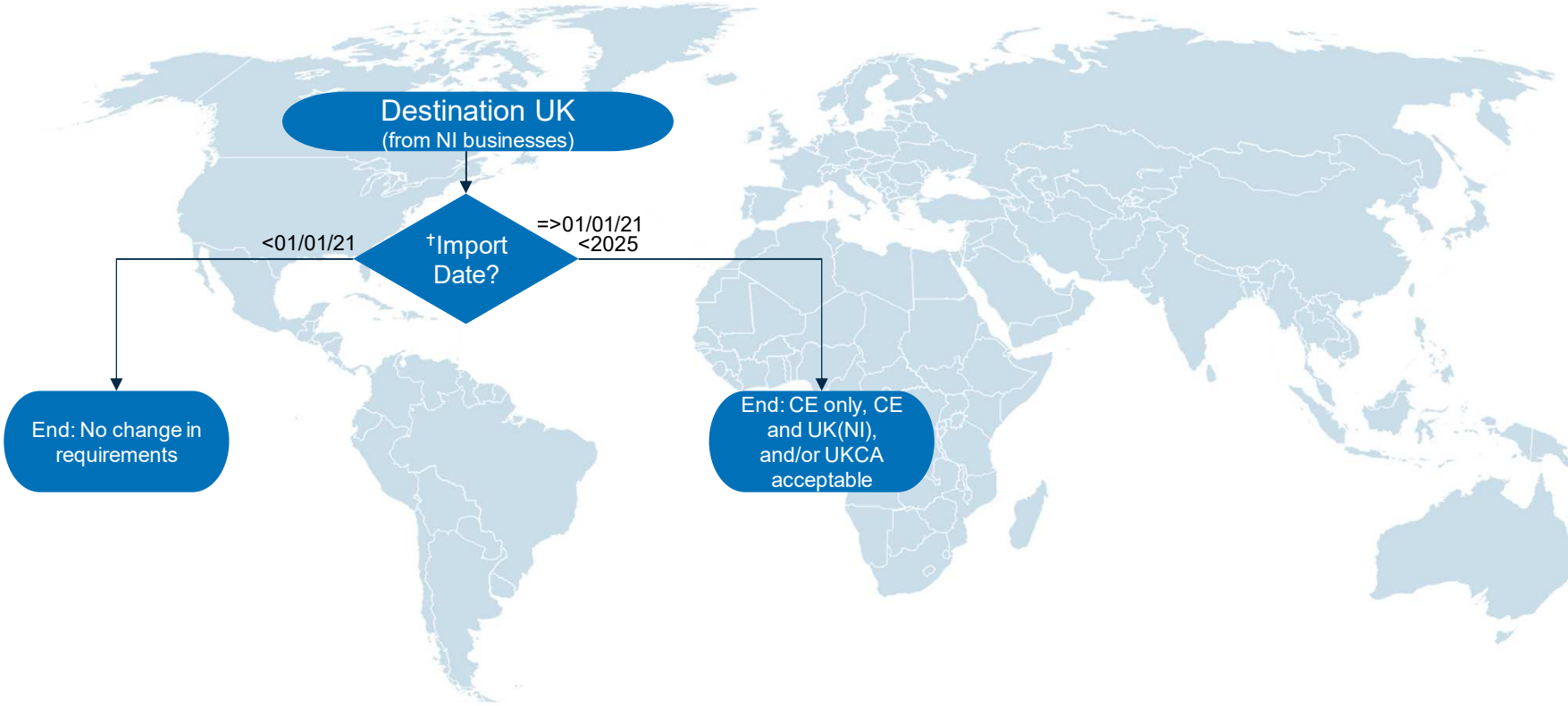
†Or date placed on market if product is already in UK.

TÜVRheinland®
Precisely Right.

5. Origin, Destination and Requirements

Movement of Products: Destination UK from NI Businesses

Does not apply to Products with **Special Rules:**
Medical Devices
Rail Interoperability
Construction Products
Civil explosives



†Or date placed on market if product is already in UK.

TÜVRheinland®
Precisely Right.

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

6. Case Study 1 – Made in Scotland, Sold across UK and EU.

Bob's Kitchen Appliances Ltd.

Initial Situation:

Bob's Kitchen Appliances Ltd. is a manufacturing company that make kitchen appliances in Scotland. They have designed a **new toaster which they are planning to launch in February 2022** and their **target market is the UK and EU**. Bob from Bob's Kitchen Appliances Ltd has been too busy designing **to keep up-to-date with the regulatory changes due to Brexit**, lucky for Bob he took some time out and joined this online seminar.

Challenges:

Bob knows his toaster falls under the Low Voltage Directive and therefore does not require a notified body, and as he has been CE marking for many years he knows the process very well… but he can see from slide 17 there will be new rules for the UK by the time he launches his new toaster. **Bob can see he will need a UKCA mark for the UK but how does he do this? What is required to affix a UKCA mark?**

Conclusion:

Bob decides to phone TÜV Rheinland UK for advice. During his call Bob **is advised that the requirements for UKCA are nearly identical to those of CE**, as long as he includes any UK differences (if any are published) during his testing for CE then he can simply use the same evidence and complete a Declaration of Conformity for the UK and apply the UKCA mark to his product in addition to the CE mark.

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

7. UK Declaration of Conformity

The UK DoC is very similar in nature to the DoC for CE

The exact details may vary depending on the applicable legislation, but should include the following:

☒	Your name and full business address or that of your authorised representative
☒	The product's serial number, model or type identification
☒	A statement, stating you take full responsibility for the product's compliance
☒	The details of the approved body which carried out the conformity assessment procedure (if applicable)
☒	The relevant legislation with which the product complies (this is UK legislation, not EU legislation)
☒	The designated standards (UK standards not the EU standards)*
☒	Your name and signature
☒	The date the declaration was issued
☒	Supplementary information (if applicable)

Bobs Appliances

UK CA

UK DECLARATION OF CONFORMITY

We: Bobs Kitchen Appliances Ltd

of: 862 Turnabout Rd, Inverness, Scotland, IV1 9PH

as manufacturers declare, under our sole responsibility, that the product(S)

Product Name(S): **Super Toaster**

Model Number(S): **ST-2-Silver, ST-2-Black, ST-2-RED**
ST-4-Silver, ST-4-Black, ST-4-RED

conform with the following standards:

BS EN 60335-1:2012+A2:2019
BS EN 60335-2-48:2003+A2:2019
BS EN 55014-1:2017+A11:2020
BS EN 55014-2:2015
BS EN IEC 63000:2018

and, the product(s) herewith complies with the requirements of the following UK legislation:

Electrical Equipment Safety Regulations 2016
Electromagnetic Compatibility Regulations 2016
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

B Bobby

Inverness, 1st January 2021
Place, Date of issue

Mr. B. Bobby, Managing Director
(authorised signature)

Note: *EU and UK DoC should be separate documents and not merged into one.*

- BSI's current membership of CEN and CENELEC runs until the end of 2021, and they are confident that they will be able to extend their membership well beyond that.

More info can be found here: https://www.bsigroup.com/en-GB/about-bsi/uk-national-standards-body/standards-and-eu-exit/

TÜVRheinland®
Precisely Right.

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

8. Case Study 2 - Made in China. Sold across UK, NI and EU

Super Safe Ltd.

Initial Situation:

Super Safe Ltd manufacture PPE in the China, they have just released a new face mask and they expect to produce the product for more than 5 years. **The target market for the mask is the EU and UK (including Northern Ireland). They have used an EU notified body for their required testing, marked the product with the CE mark and have issued an EU DoC.**

Challenge:

Super Safe Ltd have identified that Northern Ireland will continue to accept CE for the foreseeable future - so no extra requirements exist there. They can also see that they can continue to sell their product to the rest of the UK until the end of 2021 with no further action because they used an EU notified body for conformity assessment. However Super Safe are a proactive company and **decide they will add the UKCA mark in mid 2021**.

Conclusion:

As a UK Approved body is required for face masks from the start of 2022 onwards for the UK, they investigate their options. They can either have their testing repeated with a UK Approved body or they can submit their already complete test reports and certification from their EU notified body to a UK Approved body for review and certification. They decide to take the second option to save on the cost of repeat testing.
Being a loyal TÜV Rheinland UK **Client** Super Safe Ltd **decide they will submit their Certificate and test report to TUV Rheinland UK Ltd* for UK certification in mid 2021, once TUV Rheinland UK Ltd issues the certification they can create the UK DoC and apply the UKCA mark to the product.**

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

4. Legislations covered under UKCA

List Product Types covered by UKCA

Product Types		
Toys Safety	Recreational craft and personal watercraft	Electronmagnetic compatibility
Personal protecitve equipment	Machinery	Radio Equipment
Gas Appliances	Lifts	Ecodesign
Low voltage electrical equipment	Pressure Equipment	Aerosols
Non-automatic weighing instruments	Simple pressure vessels	Outdoor Noise
Measuring instruments	ATEX	Restriction of hazardous substances

Products covered by UKCA

with special rules

- Medical Devices
- Construction Products
- Rail Interoperability
- Civil Explosives

UK Energy Labelling: https://www.gov.uk/guidance/create-an-energy-label

TÜVRheinland®
Precisely Right.

10. Product covered by the UKCA marking with special rules

Medical Devices

Summary of key requirements for placing a medical device on the Great Britain market

From 1 January 2021, there will be a number of changes to how medical devices are placed on the market in Great Britain.

These are:

1.	CE marking will continue to be used and recognised until 30 June 2023
2.	Certificates issued by European Economic Area (EEA)-based Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
3.	A new route to market and product marking will be available for manufacturers wishing to place a device on the Great Britain market from 1 January 2021
4.	From 1 January 2021, all medical devices and in vitro diagnostic medical devices (IVDs) placed on the UK market will need to be registered with the MHRA. There will be a grace period for registering: ▪ 4 months for Class IIIs and Class IIb implantables, and all active implantable medical devices ▪ 8 months for other Class IIb and all Class IIa devices ▪ 12 months for Class I devices (where MHRA registration is not currently required).
5.	The above 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.
6.	If you are a manufacturer based outside the UK and wish to place a device on the UK market, you will need to establish a UK Responsible Person who will take responsibility for the product in the UK.

Note: More on MHRA: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

10. Product covered by the UKCA marking with special rules

EcoDesign and Energy Labelling

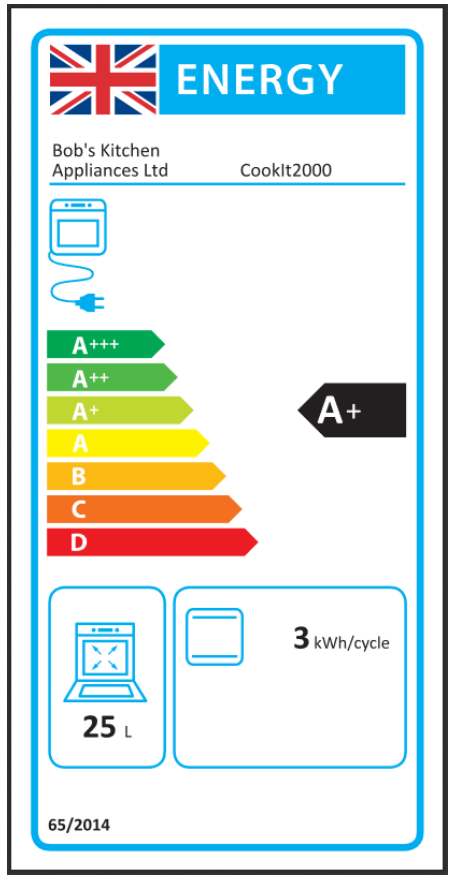
Summary of key changes

From 1 January 2021, there will be a number of changes

These are:

1.	GB (Great Britain) suppliers to the EU will need to enter information on the EU products database (EPREL) via an EU importer or EU Authorised Representative.
2.	Products placed on the GB market will not be required to be entered on to the EU products database (EPREL).
3.	Northern Ireland will continue to align with EU requirements and must comply with relevant EU legislation.
4.	From 1 January 2021, all Energy labelled devices placed on the GB market will need to meet UK legislation. This includes: ▪ UK Branding ▪ English Text ▪ Where QR codes are used, they must link to the required information on a publicly accessible website.
5.	Products placed on the GB market before 1st Jan 2021 will not need to meet these requirements

Create a GB energy label: https://www.gov.uk/guidance/create-an-energy-label



TÜVRheinland®
Precisely Right.

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

REACH

Not part of UKCA but some basics below due to popular demand

UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), the UK's independent chemicals regulatory framework, starts on 1 January 2021.

Anyone making, selling or distributing chemicals in the UK and the EU needs to follow UK REACH and EU REACH rules.

1. GB-based companies currently registered with EU REACH will no longer be able to sell into the EEA market without transferring their registrations to an EU/EEA-based organisation.
   Under UK REACH, manufacturers and importers have a duty to register chemicals that access the UK market.
2. EU REACH registrations held by UK-based companies will carry across directly into UK REACH (grandfathering)
3. UK downstream users (who do not hold an EU REACH registration) currently importing chemicals from an EU/EEA country need to ensure the substances they purchase are covered by a valid UK REACH registration.
4. These UK downstream users must notify the HSE using a Downstream User Import Notification (DUIN) of their intention to continue importing substances from the EU/EEA by 27 October 2021. www.hse.gov.uk
5. GB-based entities currently holding EU REACH registrations can continue exporting substances or mixtures to the EU/EEA markets after 1 January 2021 by either:
   - transferring their registrations to an EU/EEA-based entity
   - supporting their EU/EEA-based importers to become registrants

Note: UK GOV Guidance: https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

12.How TÜV Rheinland UK supports you

You have various options

1 Information

Cant find the information you need? Seen conflicting information?

- Get in contact with us, were happy to help.

2 Gap Analysis

Not sure where to start?

- We can assist by performing a gap analysis to identify what you are missing.

3 Readiness review

Think your ready but want another set of eyes to take a look?

- no problem we can do that.

4 Need an EU notified body?

TÜV Rheinland UK has multiple EU notified bodies

- We can assist you with any queries, testing or certification you need.

5 Need a UK Approved Body?

TÜV Rheinland UK Ltd is in the process of gaining UK Approved Body status for a wide range of regulations

- so we can be there to assist you with your transition

TÜVRheinland®
Precisely Right.

Agenda UKCA and UK(NI) Mark

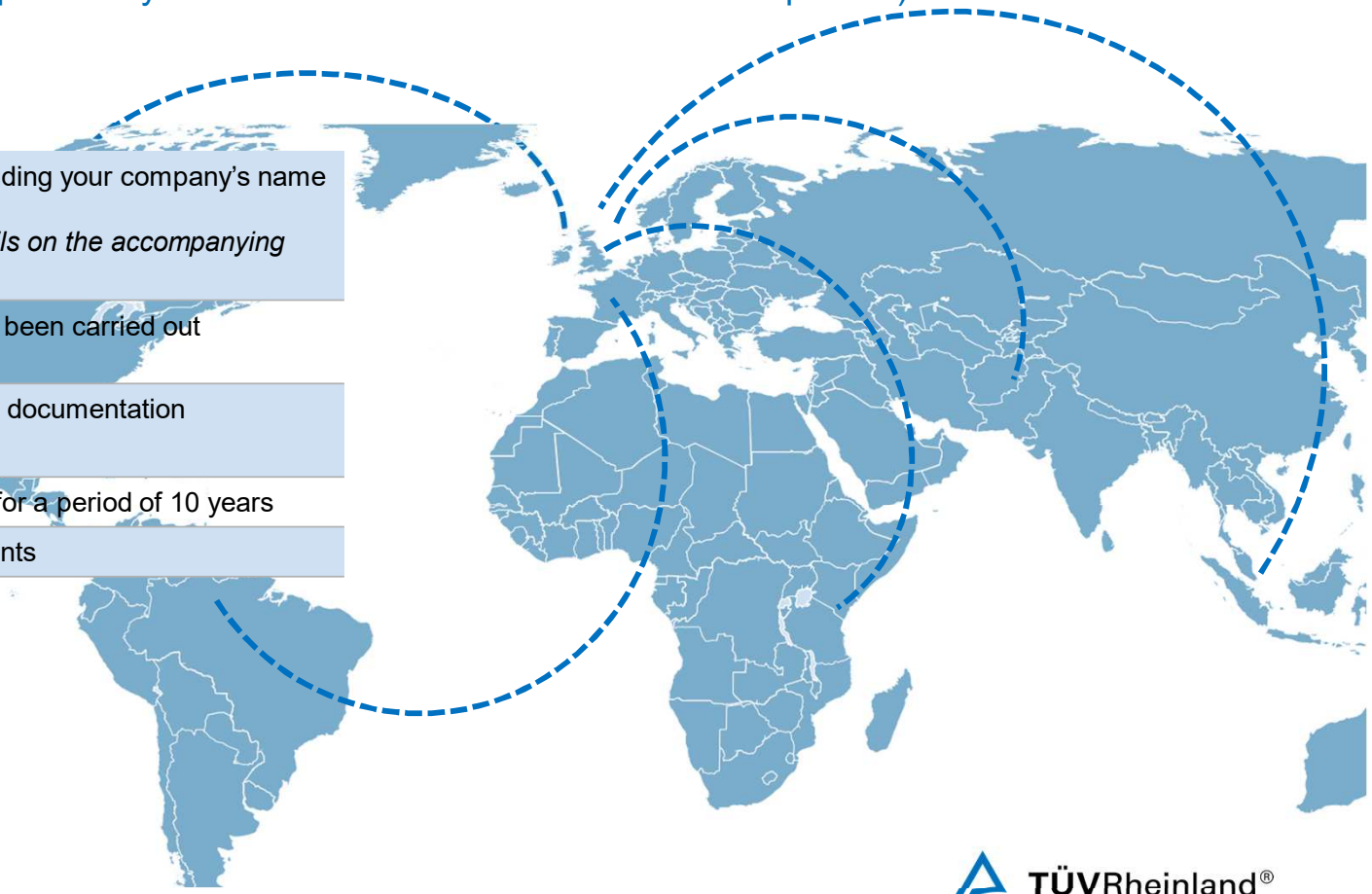
TÜVRheinland®
Precisely Right.

General Info: Importer Responsibilities

You'll become an importer if you're the one bringing goods into the UK from outside the UK and placing them on the market in Great Britain (some companies that were previously considered distributors will become importers)

You will need to confirm the following…

- ☑ Goods are labelled with your company's details, including your company's name and a contact address
  (until 31 December 2022 you can provide these details on the accompanying documentation rather than on the good itself)
- ☑ The correct conformity assessment procedures have been carried out and goods have the correct conformity markings
- ☑ The manufacturer has drawn up the correct technical documentation and complied with their labelling requirements
- ☑ You maintain a copy of the declaration of conformity for a period of 10 years
- ☑ Goods conform with the relevant essential requirements

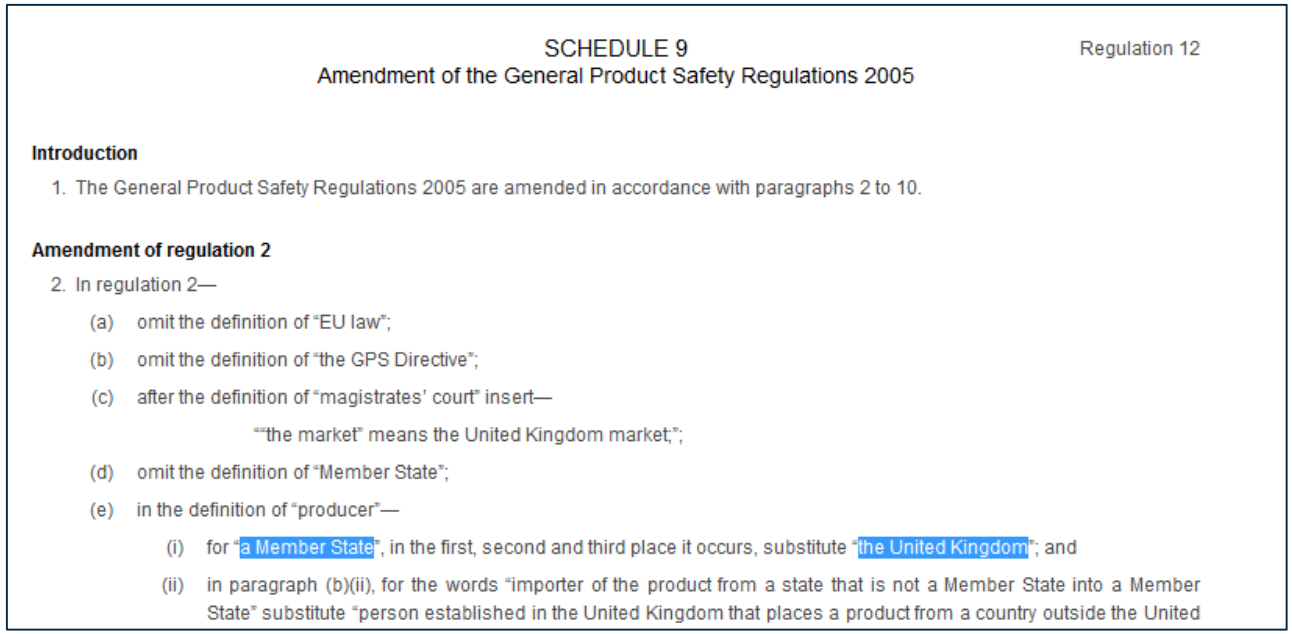


TÜVRheinland®
Precisely Right.

General Info: “Old Approach” Directives

Government guidance withdrawn on 01/10/2020

- Government will publish new guidance depending on outcome of negotiations…
- Some amendments have already been made and can be seen in ‘The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019’ www.legislation.gov.uk/uksi/2019/696/made
- The example shows how the directives have been amended:
- UPDATE: some guidance now published for Chemicals, Medicines, Vehicles, Aerospace



SCHEDULE 9 — Regulation 12

Amendment of the General Product Safety Regulations 2005

Introduction

1. The General Product Safety Regulations 2005 are amended in accordance with paragraphs 2 to 10.

Amendment of regulation 2

2. In regulation 2—

(a) omit the definition of “EU law”;

(b) omit the definition of “the GPS Directive”;

(c) after the definition of “magistrates’ court” insert—

““the market” means the United Kingdom market;”;

(d) omit the definition of “Member State”;

(e) in the definition of “producer”—

(i) for “a Member State”, in the first, second and third place it occurs, substitute “the United Kingdom”; and

(ii) in paragraph (b)(ii), for the words “importer of the product from a state that is not a Member State into a Member State” substitute “person established in the United Kingdom that places a product from a country outside the United

Guidance on Chemicals, Medicines, Vehicles, and aerospace: https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021

Agenda UKCA and UK(NI) Mark

TÜVRheinland®
Precisely Right.

13. Conclusions and Q&A

We offer effective BREXIT solutions – Time for your Questions

We discussed with you the major challenges
in the context of conformity of products and associated import/export requirements

UKCA / UK(NI) Marks

Terms

EU vs UK Directives/ Legislation

Origin, Destination and Requirements

Declaration of Conformity

General Info/ Import Requirements for UK (NI)

Products with special Rules

Medical Devices

REACH

Case Study 1: Made in the UK

Case Study 2: Made in China

TÜVRheinland®
Precisely Right.

Thank you for your kind attendance !

Contact us for your individual inquiries

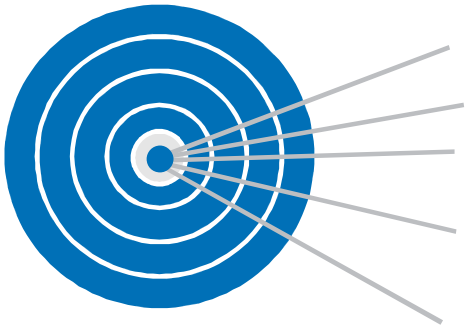
We look forward to the pleasure of doing business wth you in the near future.

Email: Safety@uk.tuv.com

Phone (General Enquiries): **+44 (0) 121 796 9411**

or contact your local TUV Rheinland office

https://www.tuv.com/brexit



Information

Gap Analysis

Readiness Reviews

Need for an EU Notified Body

Need a UK Approved Body

Providing excellent online educational quality is a top priority for us.
Thank you for taking your time to participate in our online attendee satisfaction survey which appears in a few secs !
Your valuable input will assist us in continuously evaluating the areas of improvement for our future digital events.

TÜVRheinland®
Precisely Right.