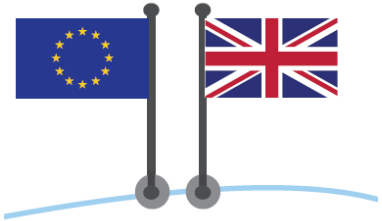

The EU-UK Trade and Cooperation Agreement (TCA):

Trading With the UK & Product Regulatory Requirements and Implications for the Supply Chain

Mary White, Head of Brexit Unit

NSAI

IEA Irish Exporters Association

GETTING IRELAND BREXIT READY

What happened on 1.1.21

- **The transition period ended and a new EU-UK Trade agreement (TCA) came into effect**
- **EU law no longer applies in UK**
  - The UK are a third country under EU law
- UK law applies to Great Britain market
- UK notified bodies are no longer recognised in the EU
- UKAS accredited certificates not valid for **harmonised** products
- ***Protocol on Ireland-Northern Ireland came into effect***

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GETTING IRELAND BREXIT READY

What hasn't changed?

- **EU regulations/directives still applies to products from UK placed on the EU market**
  - Must be **CE marked** if required by EU Rules
  - Manufacturer must use an **EU-27 notified body** if required by EU legislation
  - Have a valid EU **Declaration of Conformity for Industrial Products and Performance for Construction products**
- Self-certification by UK manufacturers is allowed
- **Irish Building Regulations** applies to products used in Irish construction projects.

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GETTING IRELAND BREXIT READY

Protocol on Ireland-Northern Ireland

- The Protocol protects the Good Friday Agreement, North/South cooperation and the all island economy.
- Has applied from **1 January 2021**.
- Avoids a hard border on the island of Ireland
- Protects Ireland's place in Single Market and Customs Union.
- Most of the changes applying to trade with **GB** do not apply to trade with **NI**
- **EU product legislation** continues to apply in **NI**
- Goods moving to/from **NI** will largely continue to do so

How the system works

Regulation

EU drafts regulations and directives which breaks down barriers to trade to facilitate the free movement of products to trade.
Obligations and responsibilities on **manufacturers, importers and distributors**

Standards Technical Specifications

Shows how you meet these requirement
Harmonised standards- **Mandatory**
Technical Specifications- voluntary

3rd Party Certification

Demonstrates that your product meets the requirements of Regulation /Directive where required.
Agreed Framework of **notified bodies**

Declaration Of Conformity & CE mark

Once the declaration of conformity has been drawn up, the manufacturer must affix a CE marking to the product. CE marking enables a product to be placed legally on the market in an EU Member state and then be traded on the EU's Single Market

Market Surveillance

Checks to ensure that products placed on the market comply with the requirements of the regulation/directive

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GETTING IRELAND BREXIT READY

Roles and Responsibilities

EU Notified Bodies : NANDO-Database

Notifying Authority

Accreditation Body

Irish Notified Bodies

Market Surveillance Authorities

https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id

Economic Operators Responsibilities

Declaration of Conformity & CE Mark			
Keep documentation for 10 years			
Ensure consistent production			
Monitor the product on the market, where appropriate			
Ensure the product is identifiable			
Indicate a contact point for the product			
Provide instructions and safety information in the appropriate languages			
Take corrective measures where necessary			
Cooperate with requests from national authorities			

New UK legal framework

- **UK legal framework** replaced EU legislation
- Apply to products in **Great Britain**
  (*England, Scotland and Wales*)
- Does not apply in NI
- **UK product legislation** similar to EU product legislation
  - **UKCA mark** replaces CE mark
  - **UK approved bodies** replace EU notified bodies
  - **UK designated standards** replace hENs
  - **UK Declaration of Conformity** replaces EU DoCs
  - UK customers of EU manufacturers become **importers**

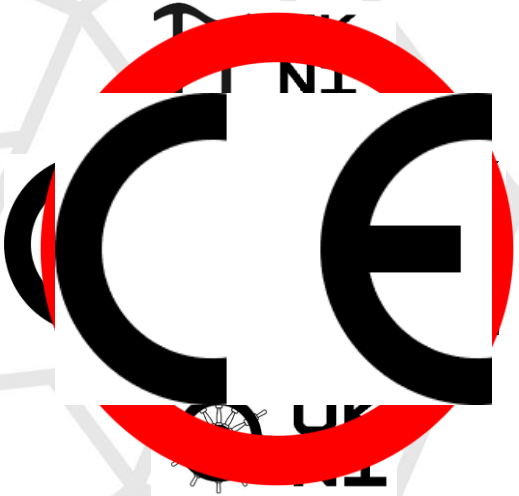
Post Brexit Changes

Great Britain

EU-27 (including Ireland)	**Great Britain** (England, Scotland and Wales)
• EU Legislation • Regulation 765/2008 • Accreditation and Market Surveillance	• UK Draft Statutory Instruments 2019 Product & Safety Metrology Amendment Schedule 33
Harmonised Standards (hENs)	Designated Standards
Notified Bodies	Approved Bodies
CE	UKCA

‘CE UK(NI)’ mark

- **Article 7** makes provision for “*…an indication in respect of Northern Ireland … shall be indicated as "UK(NI)" or "United Kingdom (Northern Ireland)*“.
- Industrial products:
  - EU legislation and hENs apply
  - certified by ‘UK notified bodies’
  - CE marked and include indication in respect of Northern Ireland
- **Products bearing the ‘CE UK(NI)’ mark cannot be placed on the Irish or EU market**
- ‘CE UK(NI)’ mark not needed if you already CE mark your product



Post Brexit Changes
Northern Ireland

EU-27 (including Ireland)	**Northern Ireland**	**Great Britain** (England, Scotland and Wales)
• EU Legislation • Regulation 765/2008 • Accreditation and Market Surveillance		• UK Draft Statutory Instruments 2019 Product & Safety Metrology Amendment Schedule 33
Harmonised Standards (hENs)		Designated Standards
Notified Bodies		Approved Bodies
CE	CE UKNI CE UKCA	UKCA

UK acceptance of CE marking

- UK product legislation has applied in **Great Britain** since **1 January 2021**
- CE marked industrial products accepted in the Great Britain until **31 December 2021**
  - EU Declaration of Conformity/Performance(Construction)
  - EU notified body certification
  - hENs
- From **1 January 2022** CE marked products no longer accepted in GB

www.ukas.com/download/brochures/UKAS-Brexit-leaflet-final.pdf

www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021

Medical Devices - UKCA Marking

- All CE marking will be valid until 30 June 2023
- UKCA marking valid from 01 January 2021
- UKCA marking mandatory from 01 July 2023

- Legislation that will apply in Great Britain will be the **UK Medical Devices Regulation 2002** (in the form that they exist on January 2021) to:

AIMDDD	90/385/EEC Active Implantable Medical Devices
MDD	93/42/EEC Medical Devices
IVDD	98/79/EC In Vitro Diagnostic Medical Devices

- UK Approved Body must be used.

Regulatory Divergence

- MDR and IVDR will not apply in Great Britain.
(*This applies in the EU from the 26th May 2021*)

Regulation (EU) 2017/745 on Medical Devices
Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

- MDR and IVDR applies in Northern Ireland under the Northern Ireland Protocol Northern Ireland will continue with the EU regulation, the MHRA will be the designating authority for the North

Roles and Responsibilities UK

UK Conformity Assessment → **UK Market Conformity Assessment Bodies (UKMCAB)**

Notifying Authority

Accreditation Body

UK Approved Bodies

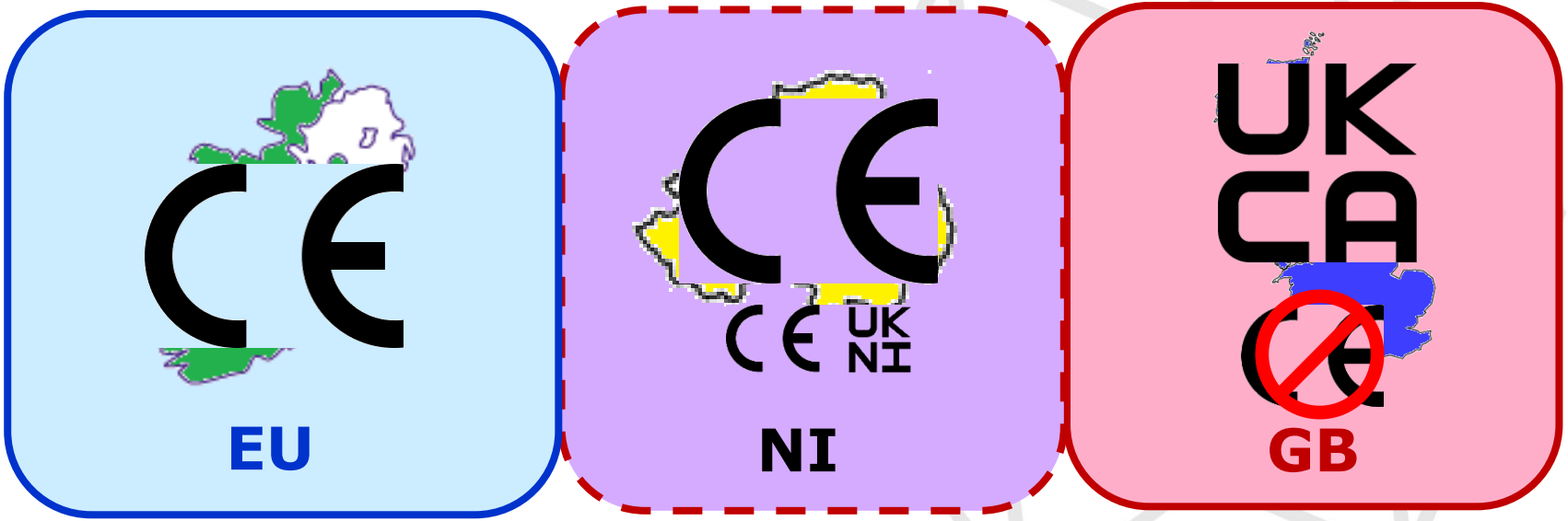
Technical Assessment Bodies

Market Surveillance Authorities

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

Assisting Irish Companies Export to GB & N.I.

What mark must I use?



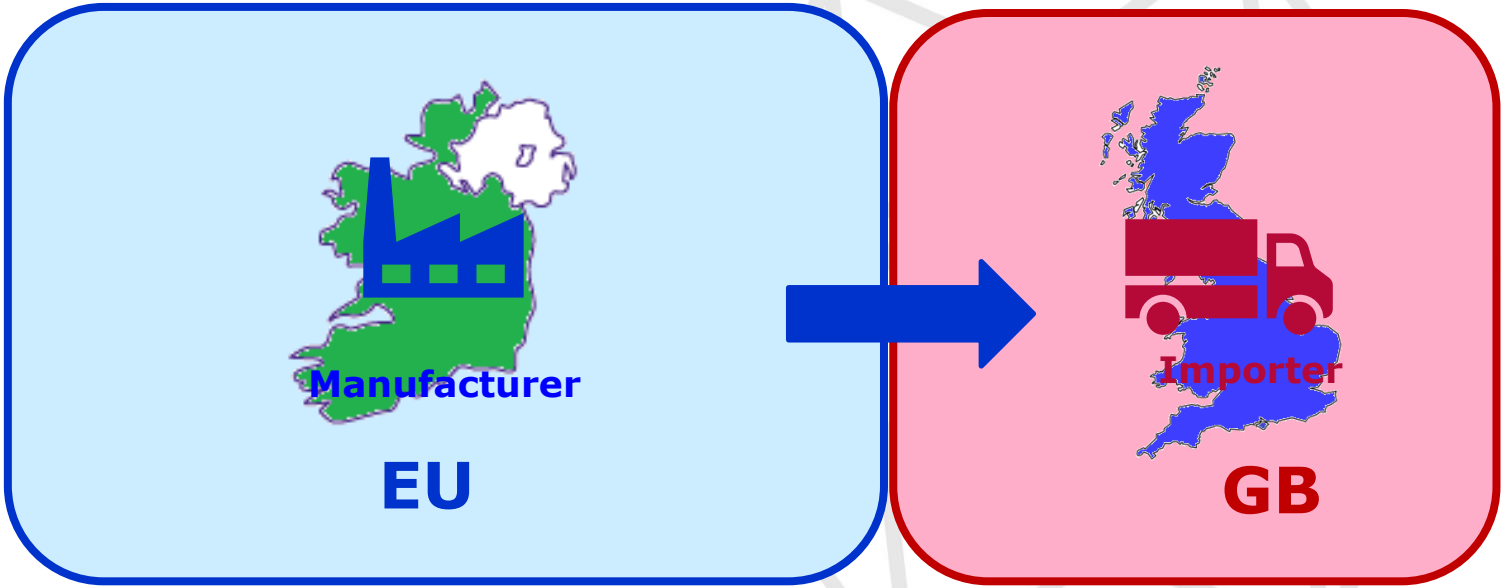
From 1 January 2021 to 31 December 2021

How Supply Chain will be impacted by Brexit

Economic Operators

- Manufacturer
- Importer
- Authorised Representative - GB manufacturer
  Responsible Person - Irish Manufacturer
  (Medical Devices)
- Distributor

Economic operators exporting into GB



Since 1 January 2021

Importing products from GB

- You will become an **importer** take on additional responsibilities. (For construction products check **article 13 of the CPR**):
  - Find out the additional responsibilities you will be taking on
  - Engage with the manufacturers of the products
  - Ensure that you will be able to get the information and assurances you need
  - Be able to access the technical file if required by market surveillance authorities
  - Your details must be included in packaging and product information leaflets

Market Surveillance Authorities

Impacts of Brexit

The EU Notice to Stakeholders (March 2020)

states the general principles that after the 31 December 2020:

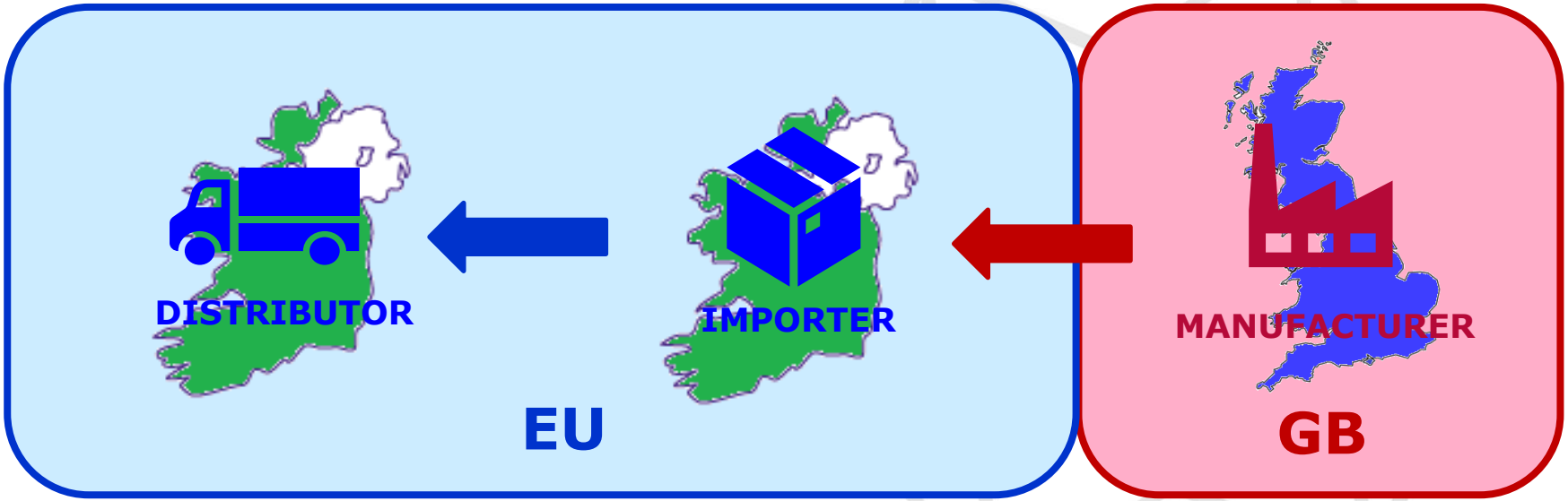
- All Economic Operators must comply with their obligations and responsibilities under Regulation (EU)765/2008 when placing a product on the EU market.
- Both Authorised Representatives and importers must be established in the EU-27*
- The EU Commission is advising that British Standards can no longer be used for product certification where the relevant EU legislation mandates the use of a **harmonised** European Standard.
- Where harmonised European Standards are not mandated manufacturers should follow the requirements set out in the relevant EU product legislation. British Standards are likely to be acceptable where the regulations allows the use of international standards, European Standards or national standards from third countries.
- The UK Accreditation Service has ceased to be a national accreditation body within the meaning and for the purposes of EU Regulation No 765/2008.
- UK Notified Bodies lost their status as EU Notified bodies on the 31st December 2020

Note: It would constitute a formal non-compliance to refer to a **BS** EN on a DoP/DoC or CE Marking if the product is being placed on the EU market.

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

https://european-accreditation.org/ea-statement-on-continuing-recognition-of-ukas-under-the-ea-mla/

Economic operators importing from GB



Since 1 January 2021

ISPM15 - Wood Packaging Materials (WPM)

- **ISPM15** sets down standards for treatment and marking of WPM (pallets, crates, dunnage etc.) used in international trade.
- **Regulation (EU) 2016/2031** sets out EU legal basis and minimum standards for the registration, authorisation, and supervision of manufacturers of WPM.

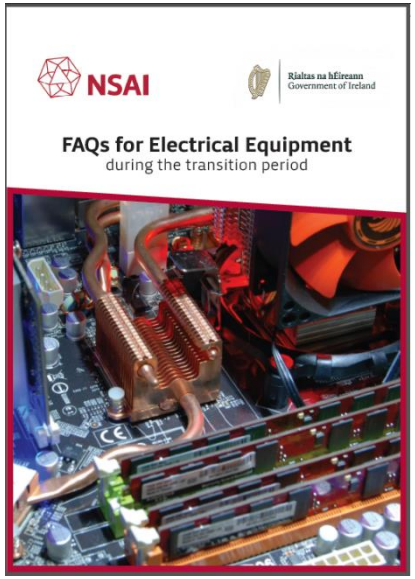
- ***WPM for imports from GB will need to meet requirements of ISPM15 from 1 January 2021.***
- ***Also applies to exports to GB from 1 January 2021.***
- ***ISPM15 will not generally apply to WPM for trade with NI (with certain exceptions)***

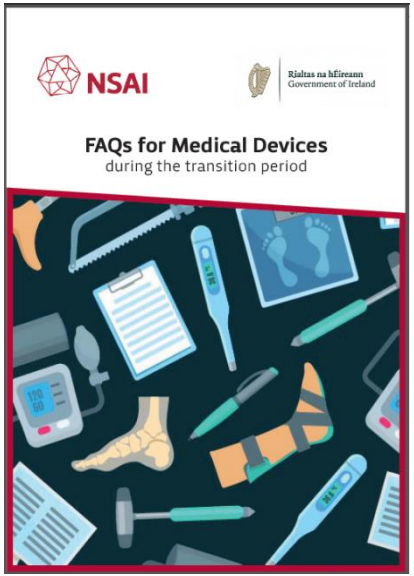
IPPC IE - 000 HT

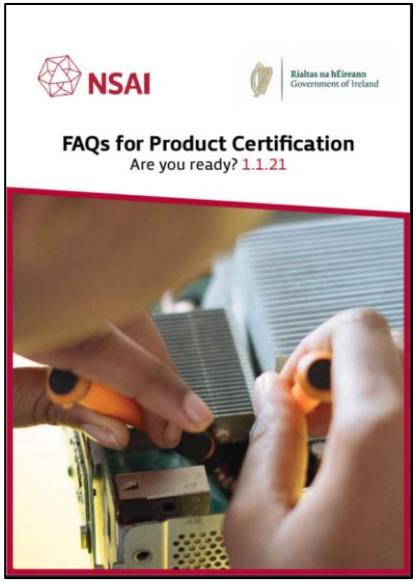
Revenue Enquiries Helpline	Points of Contact
1. Register for an EORI number	www.revenue.ie/en/online-services/services/common/register-for-an-eori-number.aspx
2. Declaration Safety and Security Exporting: Entry Summary Declaration (EXS) Importing: Entry Summary Declaration (ENS) Declarations for RoRo goods movements. Movement Reference Number (MRN) MRN related enquiries	EXSenquiries@revenue.ie ENSenquiries@revenue.ie
3. Systems Queries	eCustoms@revenue.ie
4. Pre Boarding Notifications (PBN) queries	PBNqueries@revenue.ie
5. General Brexit queries	brexitqueries@revenue.ie
6. Brexit National Helpline	01-73383685

More info on the Revenue Commissioners website:
revenue.ie/en/customs-traders-and agents/brexit/index.aspx

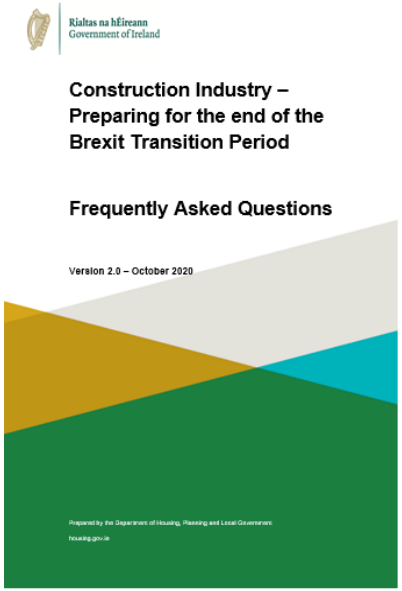
NSAI FAQs







Dept of Housing Local Government and Heritage
Published on 1 October 2020
Last updated on 31 December 2020



NSAI FAQs currently being updated

https://www.nsai.ie/brexit/brexit-resources

Further Information

EU –UK Relations:	Link
EU-UK Trade and Cooperation Agreement	https://ec.europa.eu/info/relations-united-kingdom/eu-uk-trade-and-cooperation-agreement_en
EU Relations with the United Kingdom	https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership_en
Big Changes compared to benefits of EU membership	https://ec.europa.eu/info/relations-united-kingdom/eu-uk-trade-and-cooperation-agreement_en
Protocol on Ireland/Northern Ireland	https://ec.europa.eu/commission/publications/revised-protocol-ireland-and-northern-ireland-included-withdrawal-agreement_en

The 'Blue Guide':

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG

Thank you.

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