BSI Webinar

- Introduction to CE and UKCA Marking

By Royal Charter

Welcome

Agenda

- EU Directives and Regulations
- UK Regulations
- Conformity assessment bodies
- Technical file
- Declaration of conformity
- Affixing the mark
- Roles and responsibilities
- UKCA mark, CE mark and Northern Ireland

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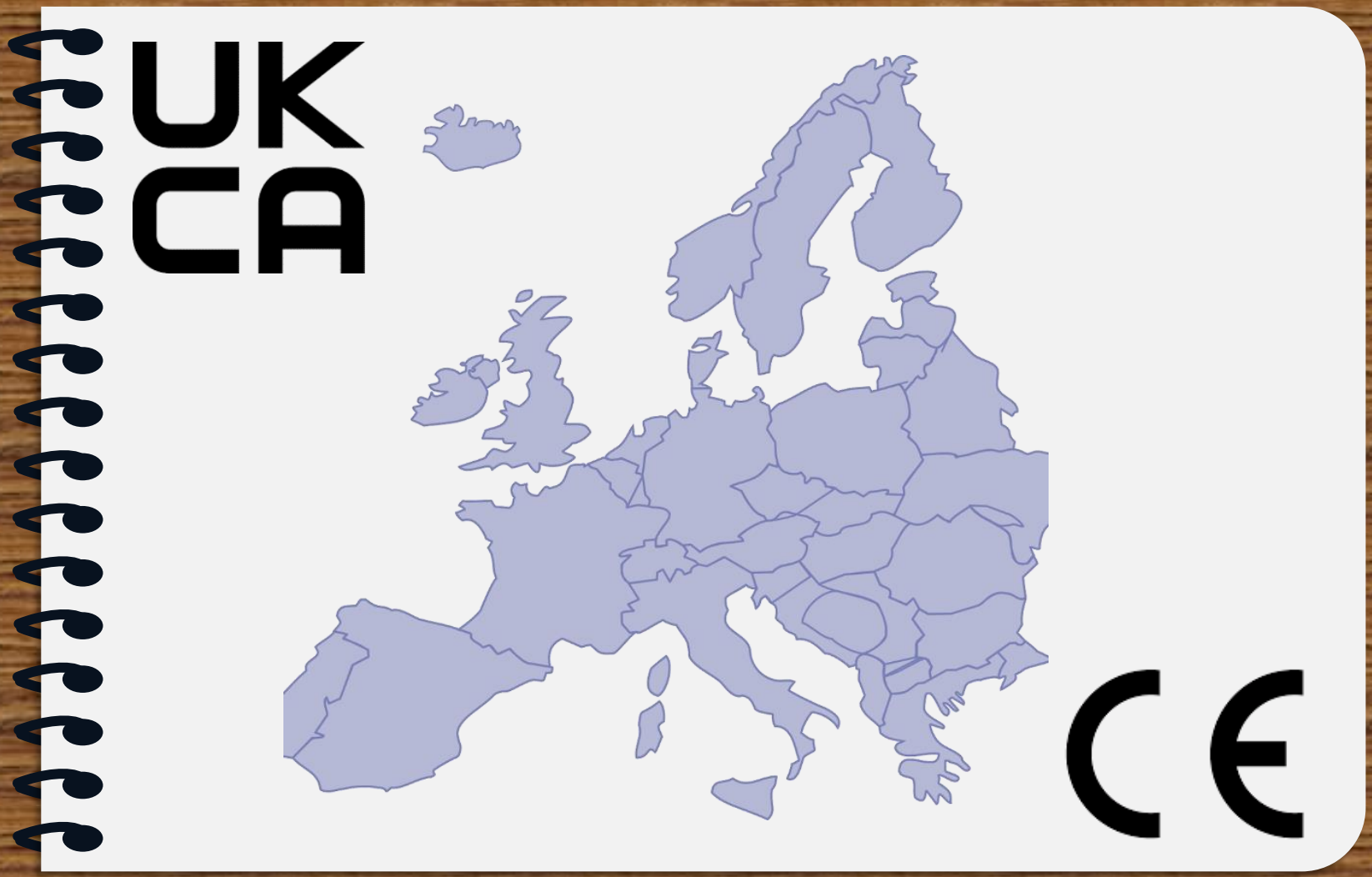
EU Directives and Regulations

Conformity marking for Europe and the UK



CE marking

Introduced in 1993 as a way to facilitate free trade of goods throughout the EEA – a common ground for product safety and performance with minimum requirements accepted in all Member States

The mark itself is a declaration by the manufacturer (or other responsible organization) that the product complies with **all relevant** European Directives/Regulations

Various Directives/Regulations cover requirements for different product types, resulting in CE marking

Different rules for different types of products

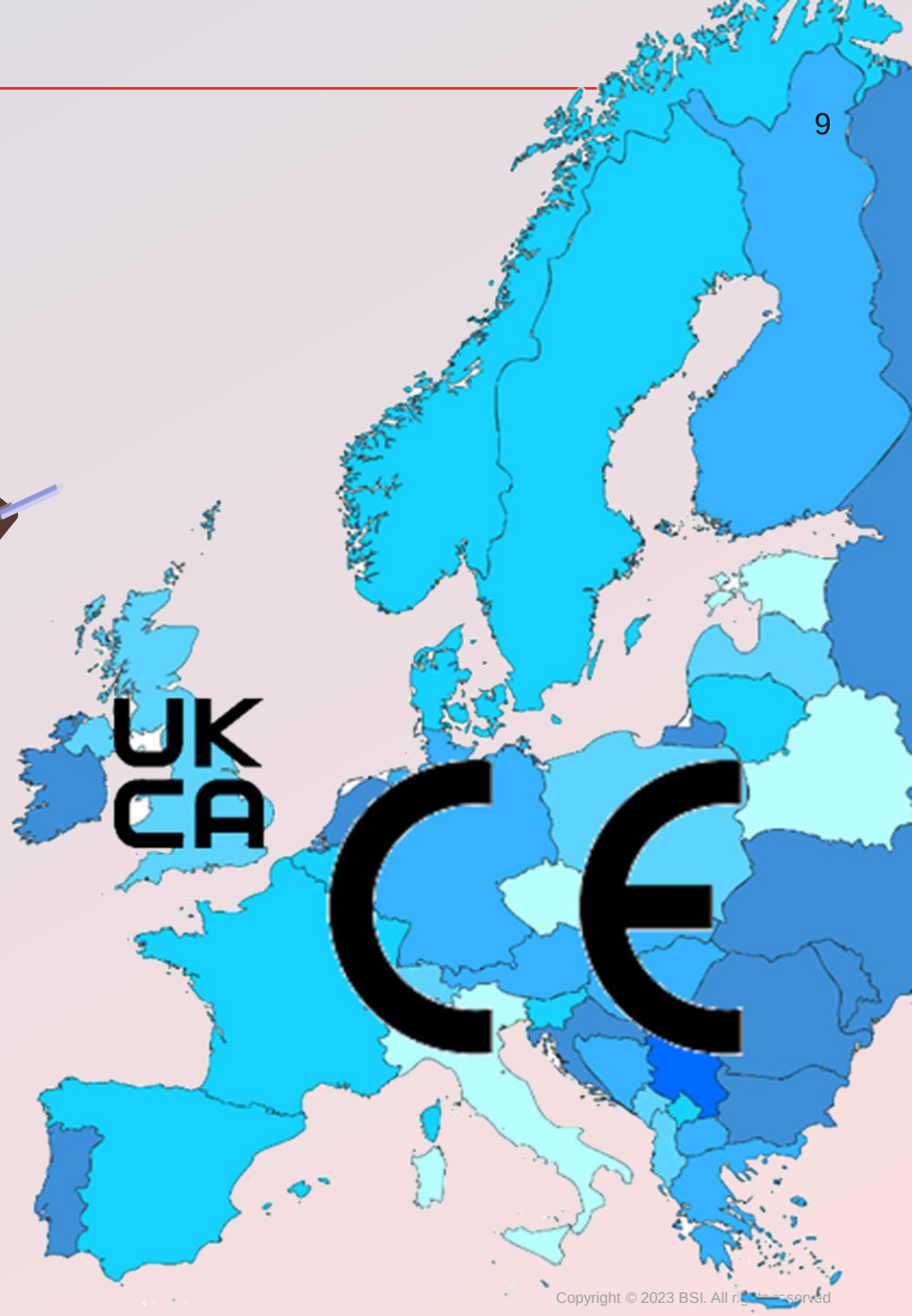
CE

CE marking – EU Directives and Regulations

UK Regulations

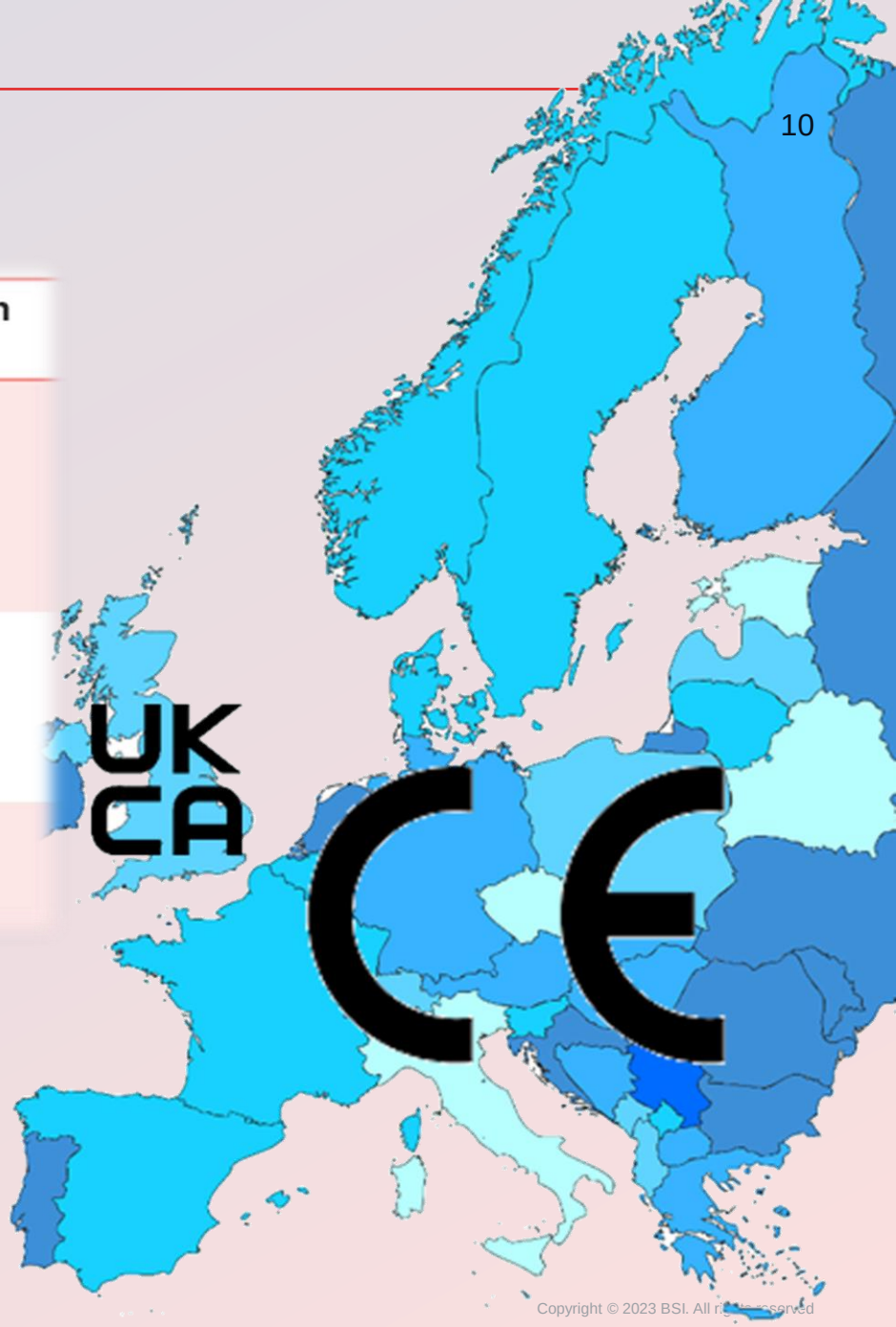
UKCA marking

Can be affixed from 1 January 2021



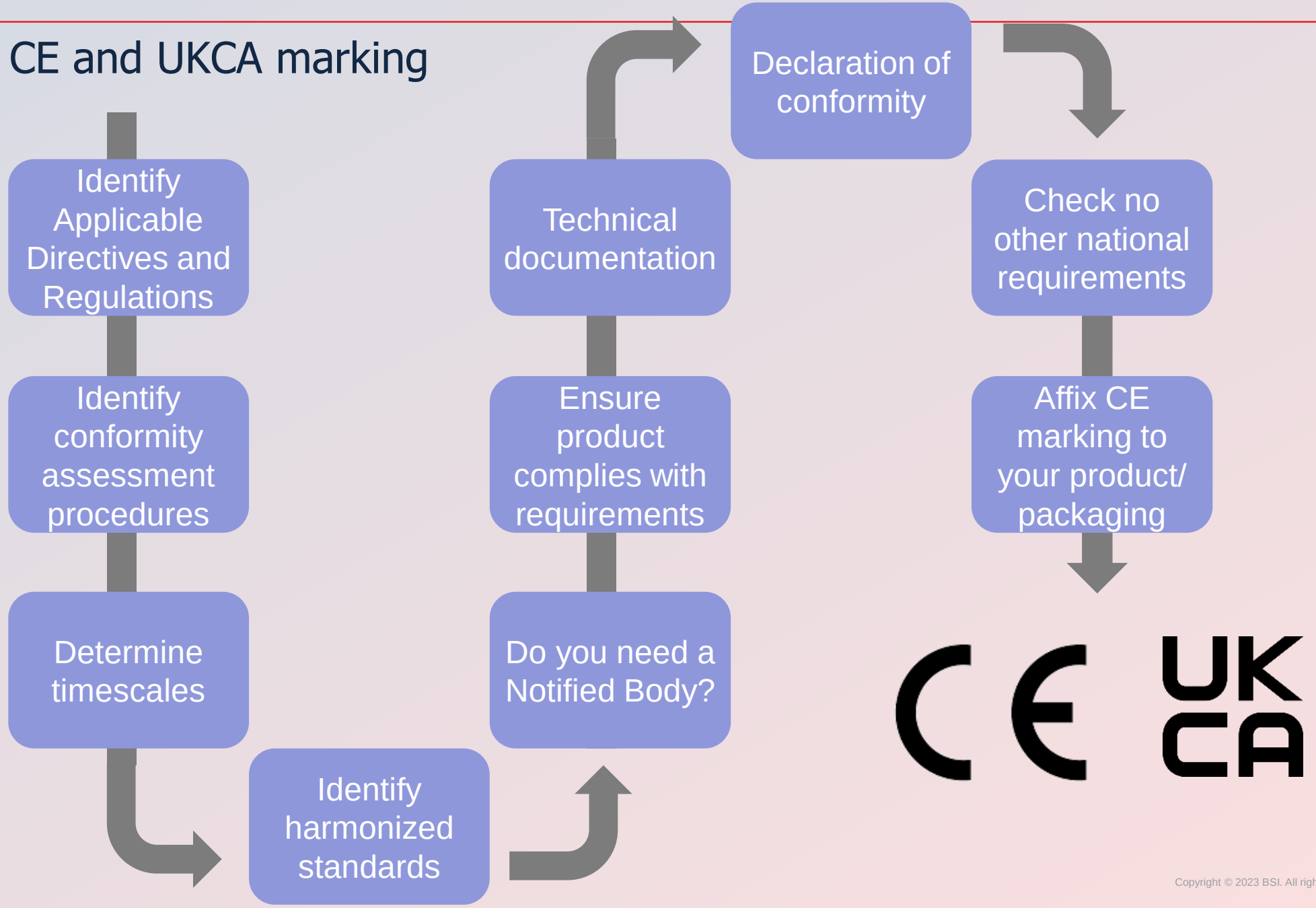
Propose Transition Timeline

Certificate	Length of transition period	End of transition period
UKCA marked under current UK regulations	Sooner of: • 3 years for general medical devices • 5 years for IVDs or when certifications expire	30 June 2028 30 June 2030
CE marked under EU directives	As above for UKCA marked devices*	As above*
CE marked under EU regulations (EU MDR and EU IVDR)	Up to 5 years	30 June 2030



UKCA marking – UK Regulations

Route to CE and UKCA marking

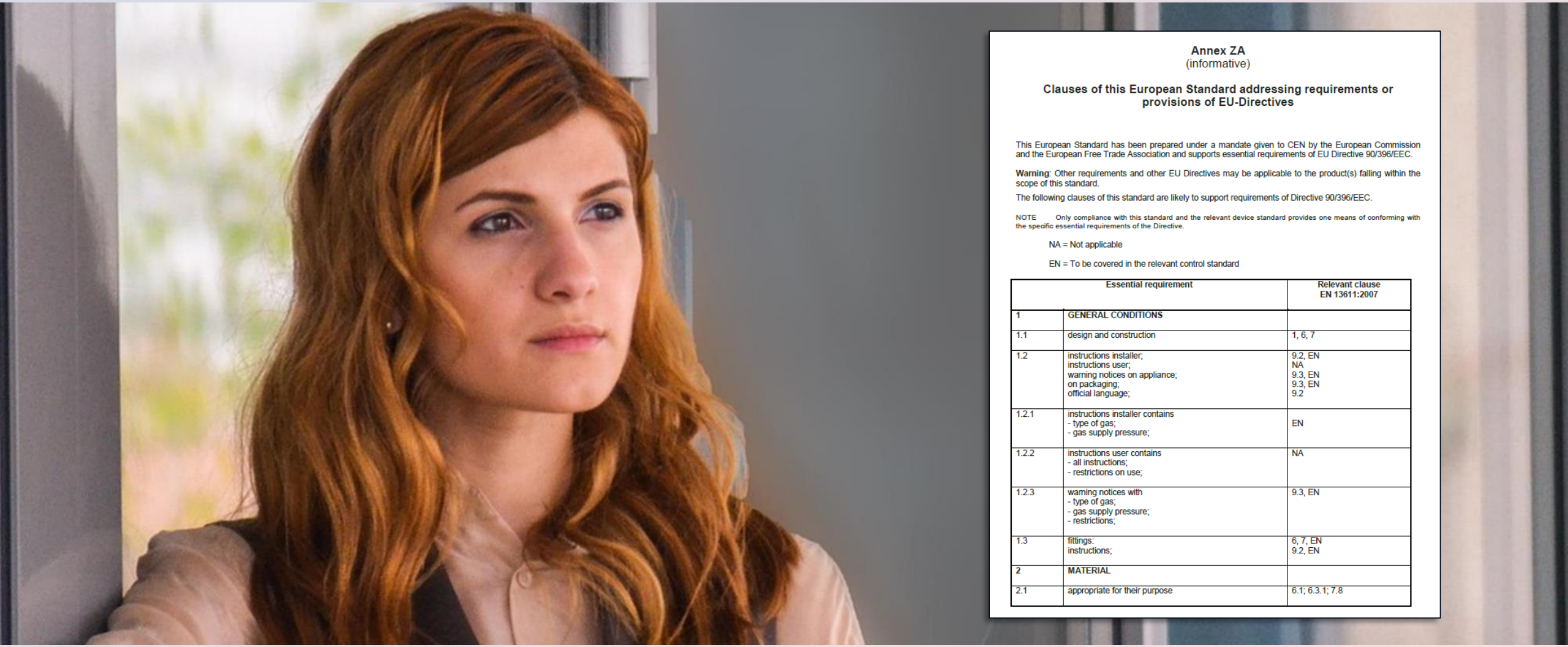


Conformity assessment

- Conformity may be demonstrated by:
  - Testing to **harmonized standards/designated standards**, or other technical specifications as appropriate
  - Third party audits of manufacturing
  - Third party product inspections
  - A combination of the above – as specified by the Directive/Regulation

- Evidence of conformity is documented in a manufacturer's **technical file**

Harmonized standards



Annex ZA
(informative)

Clauses of this European Standard addressing requirements or provisions of EU-Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 90/396/EEC.

Warning: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 90/396/EEC.

NOTE Only compliance with this standard and the relevant device standard provides one means of conforming with the specific essential requirements of the Directive.

NA = Not applicable

EN = To be covered in the relevant control standard

Essential requirement		Relevant clause EN 13611:2007
1	**GENERAL CONDITIONS**	
1.1	design and construction	1, 6, 7
1.2	instructions installer; instructions user; warning notices on appliance; on packaging; official language;	9.2, EN NA 9.3, EN 9.3, EN 9.2
1.2.1	instructions installer contains - type of gas; - gas supply pressure;	EN
1.2.2	instructions user contains - all instructions; - restrictions on use;	NA
1.2.3	warning notices with - type of gas; - gas supply pressure; - restrictions;	9.3, EN
1.3	fittings: instructions;	6, 7, EN 9.2, EN
2	**MATERIAL**	
2.1	appropriate for their purpose	6.1; 6.3.1; 7.8

Conformity assessment bodies

CE marking – Notified Bodies

Legislations Found : 31

- 90/385/EEC Active implantable medical devices PDF
- 92/42/EEC Hot-water boilers PDF
- 93/42/EEC Medical devices PDF
- 98/79/EC In vitro diagnostic medical devices PDF
- 2000/14/EC Noise emission in the environment by equipment for use outdoors PDF
- 2006/42/EC Machinery PDF
- 2009/48/EC Safety of toys PDF
- 2010/35/EU Transportable pressure equipment PDF
- Regulation (EU) No 305/2011 - Construction products PDF
- 2013/29/EU Pyrotechnic articles PDF
- 2013/53/EU Recreational craft and personal watercraft PDF
- 2014/28/EU Explosives for civil uses PDF
- 2014/29/EU Simple pressure vessels PDF
- 2014/30/EU Electromagnetic compatibility PDF
- 2014/31/EU Non-automatic weighing instruments PDF
- 2014/32/EU Measuring Instruments Directive PDF
- 2014/33/EU Lifts and safety components for lifts PDF
- 2014/34/EU Equipment and protective systems intended for use in potentially explosive atmospheres (recast) PDF
- 2014/53/EU Radio equipment PDF
- 2014/68/EU Pressure equipment PDF
- 2014/90/EU Marine equipment PDF
- 2016/797 on the interoperability of the rail system PDF
- Regulation (EU) 2016/425 Personal protective equipment PDF
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices PDF
- Regulation (EU) 2017/745 on medical devices PDF
- Regulation (EU) 2016/426 Appliances burning gaseous fuels PDF
- Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems PDF
- Regulation (EU) 2016/424 Cableway installations PDF
- Regulation (EC) No 552/2004 - Interoperability of the European Air Traffic Management network PDF
- Decision 2009/750/EC (implementing Directive 2004/52/EC) - Interoperability of Electronic Road Toll Systems PDF
- Regulation (EU) 2019/1009 on EU fertilising products

Notification Found : 11

Body :

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Notified Body number : 2797

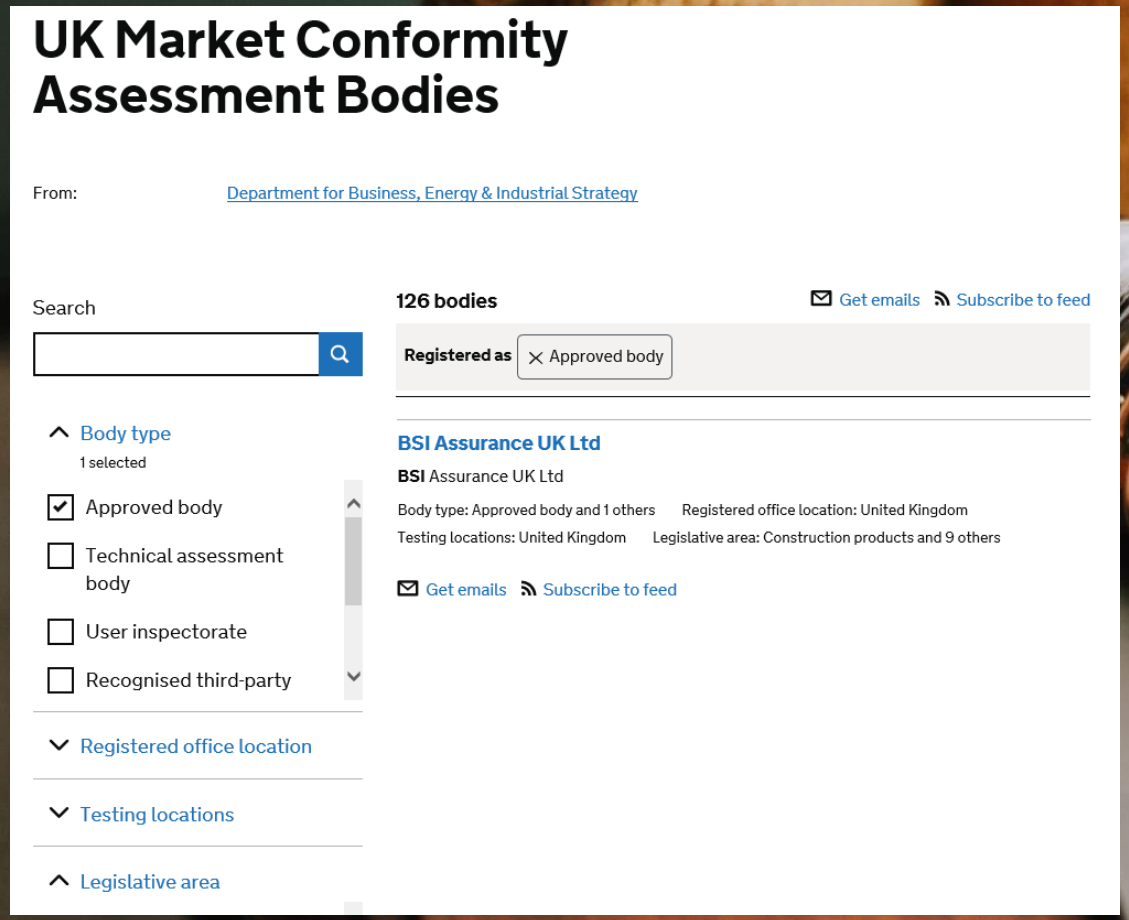
Version(s): 1 2 3 4 5

Last approval date : 27/11/2020

Legislations

90/385/EEC Active implantable medical devices	HTML	PDF
93/42/EEC Medical devices	HTML	PDF
98/79/EC In vitro diagnostic medical devices	HTML	PDF
Regulation (EU) No 305/2011 - Construction products	HTML	PDF
Regulation (EU) 2017/745 on medical devices	HTML	PDF
Regulation (EU) 2017/746 on in vitro diagnostic medical devices	HTML	PDF
2014/33/EU Lifts and safety components for lifts	HTML	PDF
2014/90/EU Marine equipment	HTML	PDF
2014/68/EU Pressure equipment	HTML	PDF
Regulation (EU) 2016/425 Personal protective equipment	HTML	PDF
Regulation (EU) 2016/426 Appliances burning gaseous fuels	HTML	PDF

UKCA marking – Approved Bodies



UK Market Conformity Assessment Bodies

From: Department for Business, Energy & Industrial Strategy

Search

126 bodies

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Registered as × Approved body

Body type
1 selected

- [x] Approved body
- [ ] Technical assessment body
- [ ] User inspectorate
- [ ] Recognised third-party

Registered office location

Testing locations

Legislative area

BSI Assurance UK Ltd

BSI Assurance UK Ltd

Body type: Approved body and 1 others Registered office location: United Kingdom

Testing locations: United Kingdom Legislative area: Construction products and 9 others

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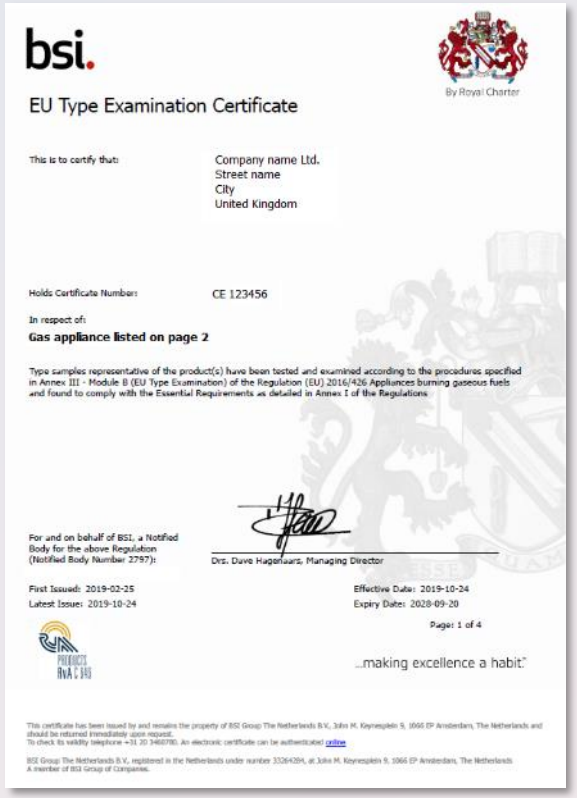
Technical file, Declaration of conformity and Affixing the mark

Technical file



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By Royal Charter

EU Type Examination Certificate

This is to certify that: Company name Ltd.
Street name
City
United Kingdom

Holds Certificate Number: CE 123456

In respect of:
Gas appliance listed on page 2

Type samples representative of the product(s) have been tested and examined according to the procedures specified in Annex III - Module B (EU Type Examination) of the Regulation (EU) 2016/426 Appliances burning gaseous fuels and found to comply with the Essential Requirements as detailed in Annex I of the Regulations.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

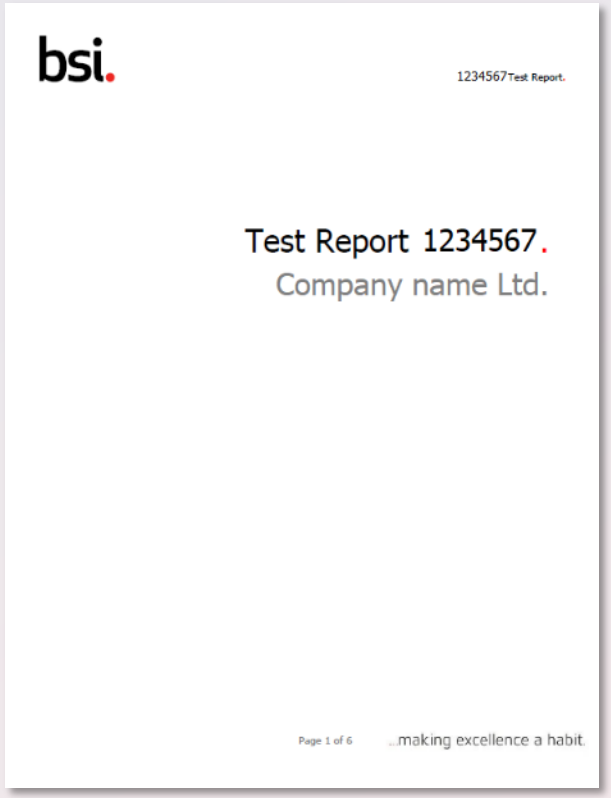
Drs. Duve Hagenaars, Managing Director

First Issued: 2019-02-25
Latest Issue: 2019-10-24

Effective Date: 2019-10-24
Expiry Date: 2028-09-20

Page: 1 of 4

...making excellence a habit.



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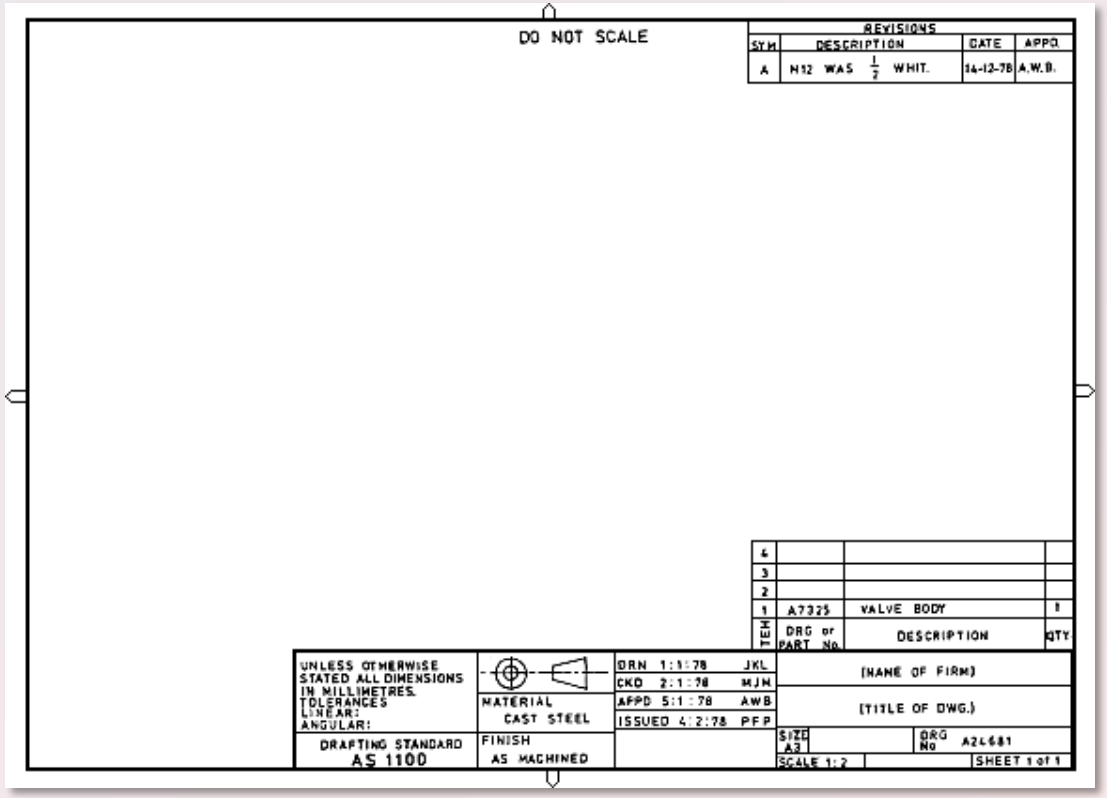
1234567 Test Report.

Test Report 1234567.
Company name Ltd.

Page 1 of 6

...making excellence a habit.



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ITEM	DRG or PART No.	DESCRIPTION	QTY
6			
3			
2			
1	A7325	VALVE BODY	1

UNLESS OTHERWISE STATED ALL DIMENSIONS IN MILLIMETRES.
TOLERANCES
LINEAR:
ANGULAR:

DRAFTING STANDARD AS 1100

MATERIAL CAST STEEL

FINISH AS MACHINED

DRN 1:1:78 JKL
CKD 2:1:78 MJM
APPD 5:1:78 AWB
ISSUED 4:2:78 PFP

(NAME OF FIRM)

(TITLE OF DWG.)

SIZE A2 | DRG No A24681

SCALE 1:2 | SHEET 1 OF 1

Declaration of conformity

EU DECLARATION OF CONFORMITY No... *

1. No... (unique identification of the product):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer
4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described above is in conformity with the relevant Community harmonization legislation: ...
6. References to the relevant harmonized standards used or references to the specifications in relation to which conformity is declared:
7. Where applicable, the notified body ... (name , number) ... Performed ... (description of intervention) ... And issued the certificate: ...
8. Additional information:

Signed for and on behalf of: .....

(place and date of issue):

(name, function) (signature):

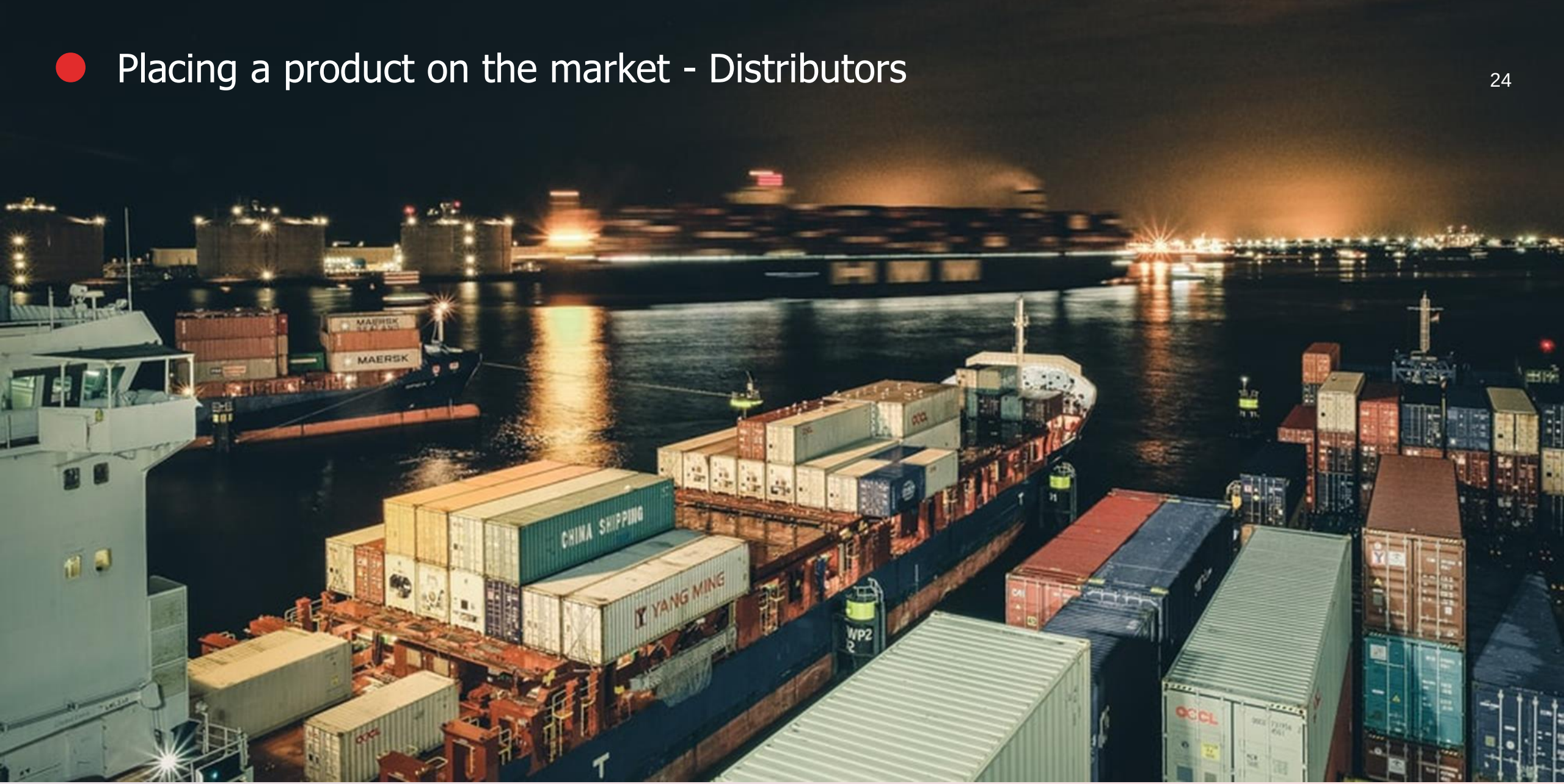
* It is optional for the manufacturer to assign a number to the declaration of conformity.

Affixing the conformity mark

Roles and responsibilities

Placing a product on the market - Manufacturers

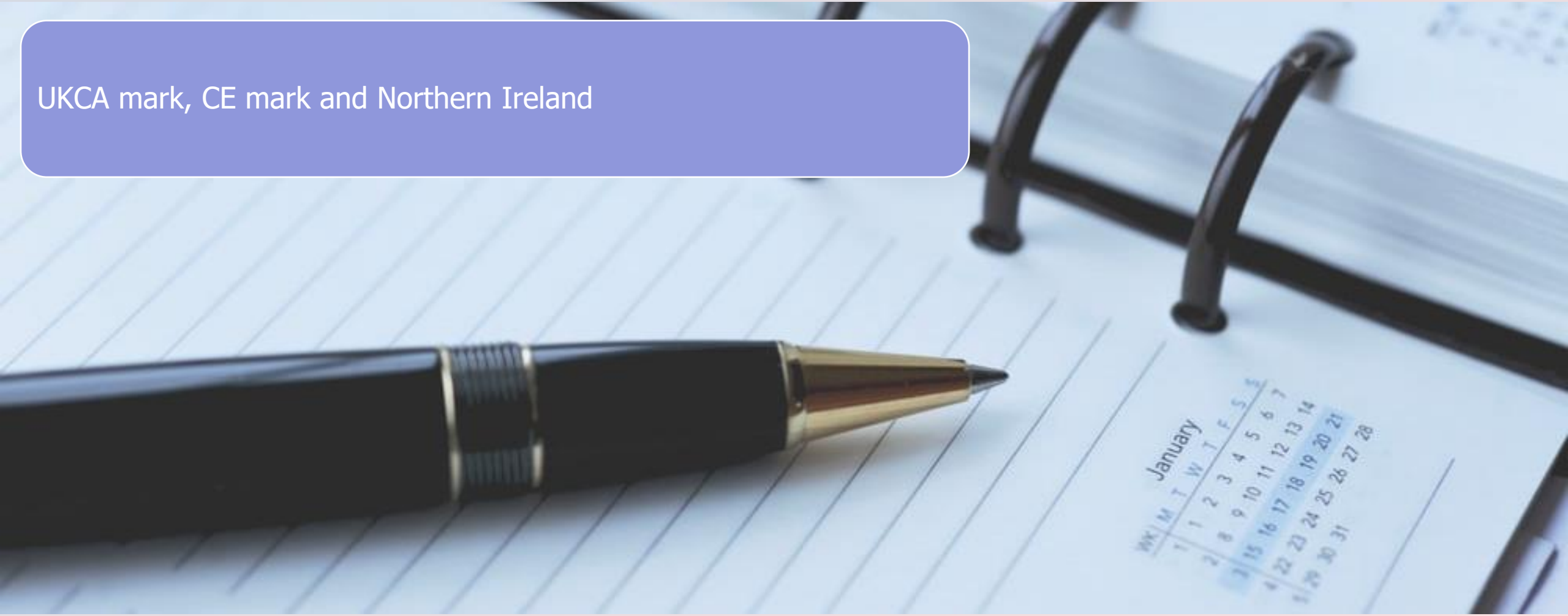
Placing a product on the market - Distributors



Placing a product on the market - Importers

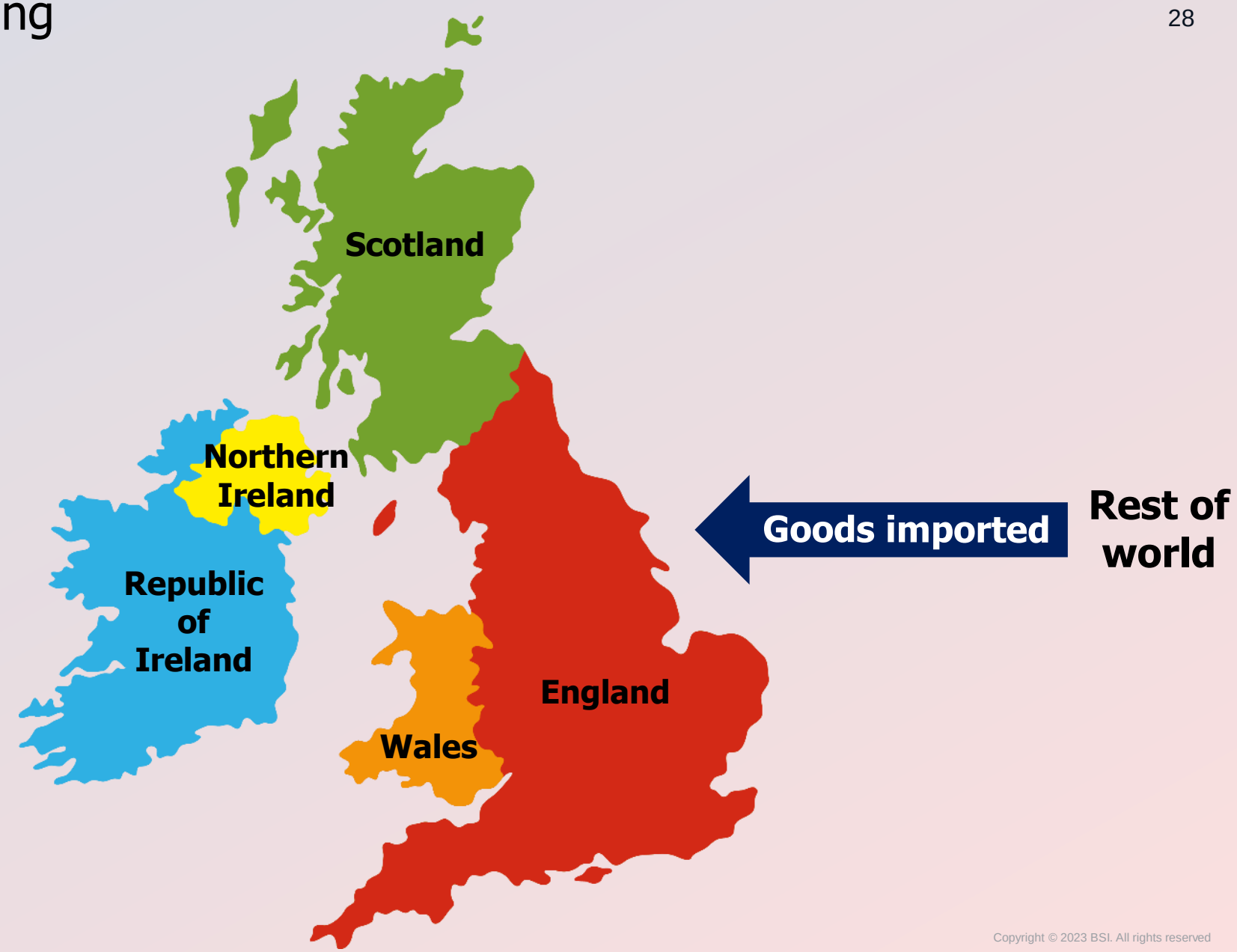
Own Brand Labeller (OBL)

UKCA mark, CE mark and Northern Ireland

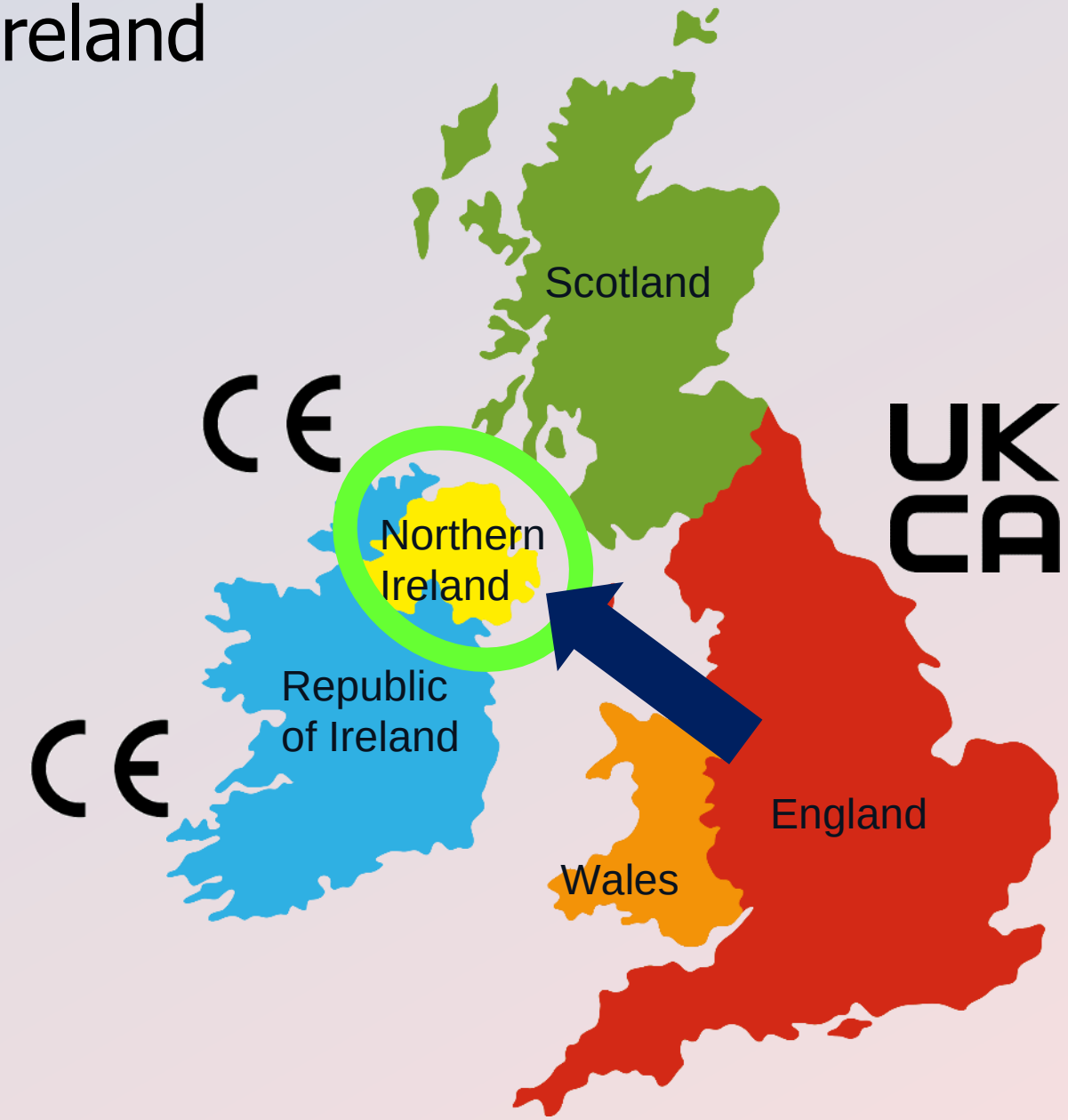


Importing and distributing

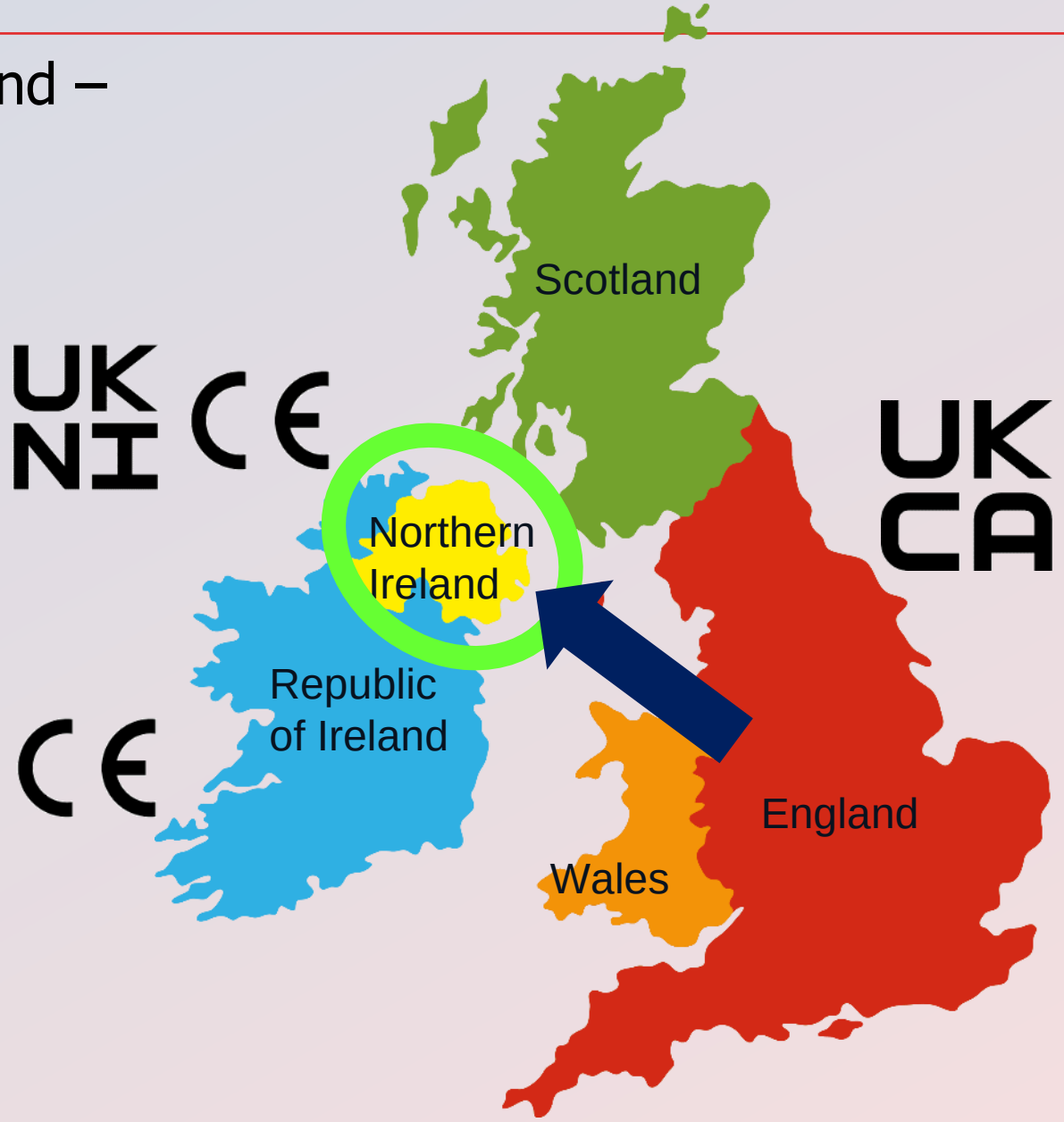
1) CE marking Regulations and Directives place responsibilities on importers
2) UKCA marking Regulations place the same responsibilities on importers



Northern Ireland



Northern Ireland – The UK(NI) mark



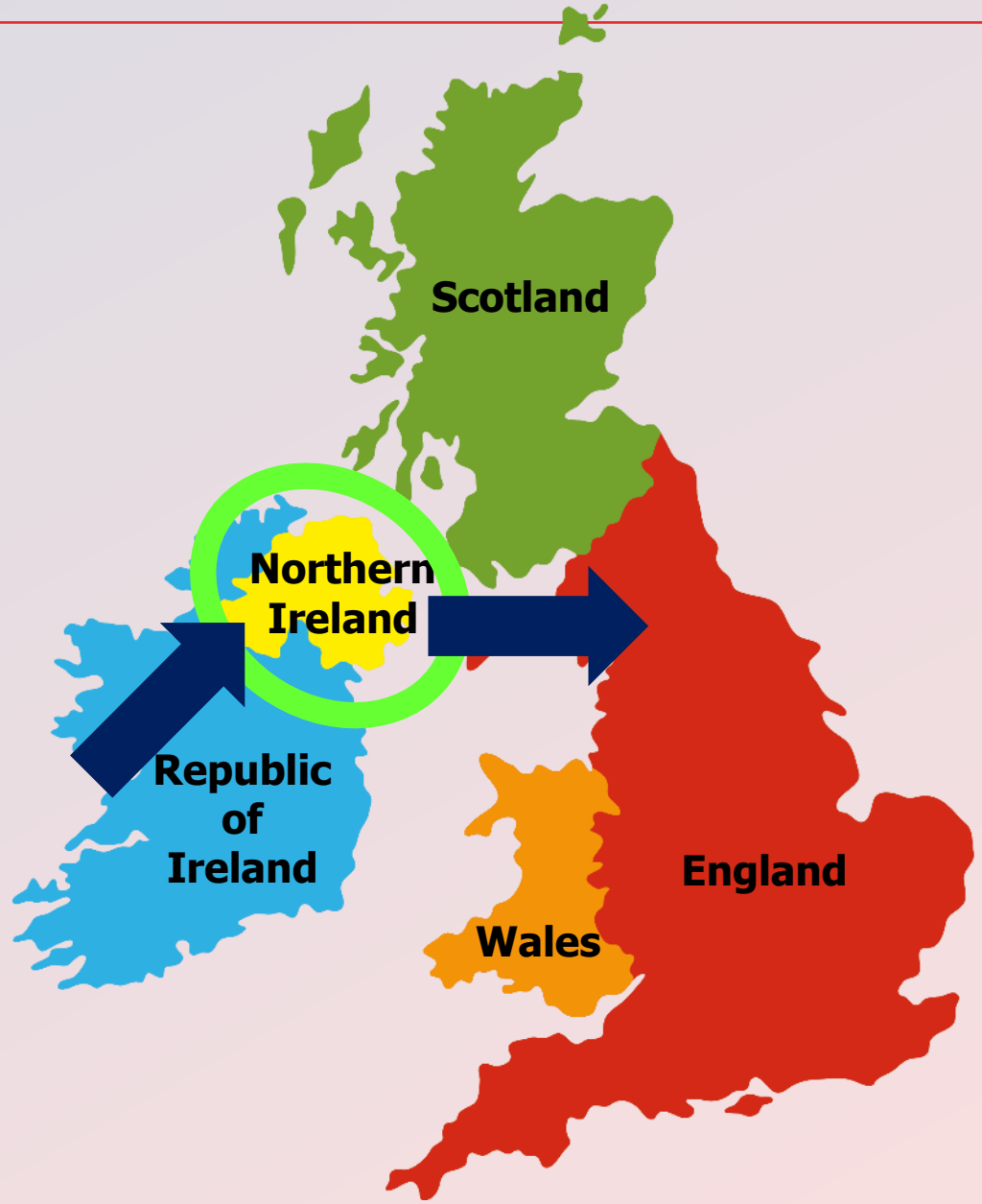
Importing and distributing

Goods of origin in the EU

NI Ireland business is distributor

But if goods then supplied on to GB the NI business becomes a UK importer

You cannot route goods through NI to avoid the UKCA Regulations in force in GB



Northern Ireland – The UK(NI) mark

Goods supplied in NI must meet EU Regulations

Goods from Europe are imported into GB

Compliance is demonstrated by CE marking, or the CE mark together with UKNI mark if you used a UK Notified Body

Contact us

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