Casus Consulting

Requirements Throughout Europe

February 2022

Casus Consulting

Topics

- What Happened to the Single Market?
- Conformity Assessment
- In-country Representation
- Labeling
- Device Registration
- Importer Requirements

Casus Consulting

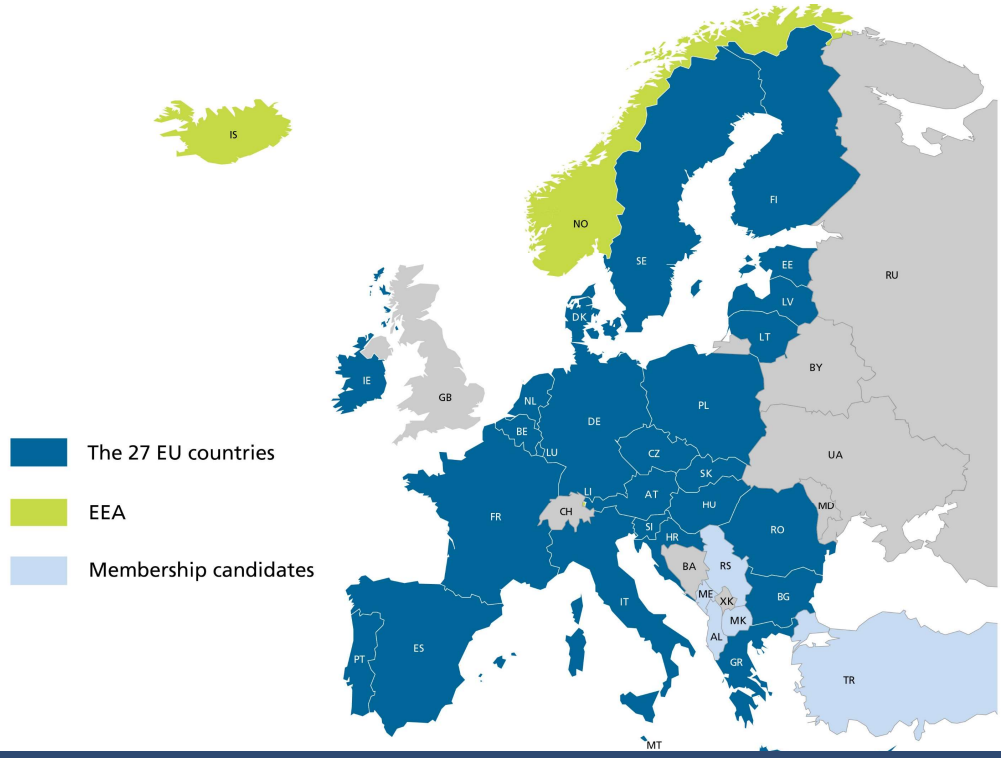
Background

Casus Consulting

What happened to the Single Market?

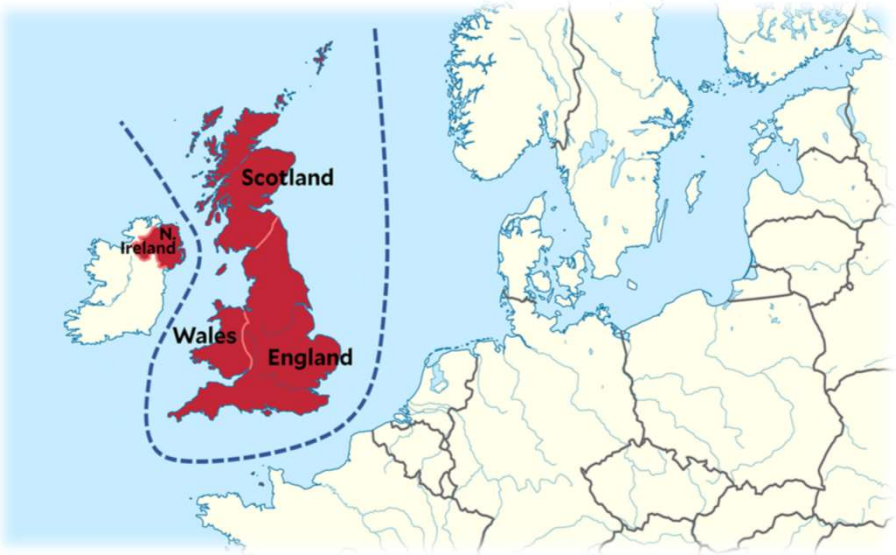
The following 36 countries used to be part of the Single Market:

- European Union (EU-27)
- European Economic Area (EEA): EU-27 + Iceland, Liechtenstein, Norway
- Turkey
- *United Kingdom: England, Northern Ireland, Scotland and Wales*
- *Switzerland*



Casus Consulting

What happened to the Single Market?

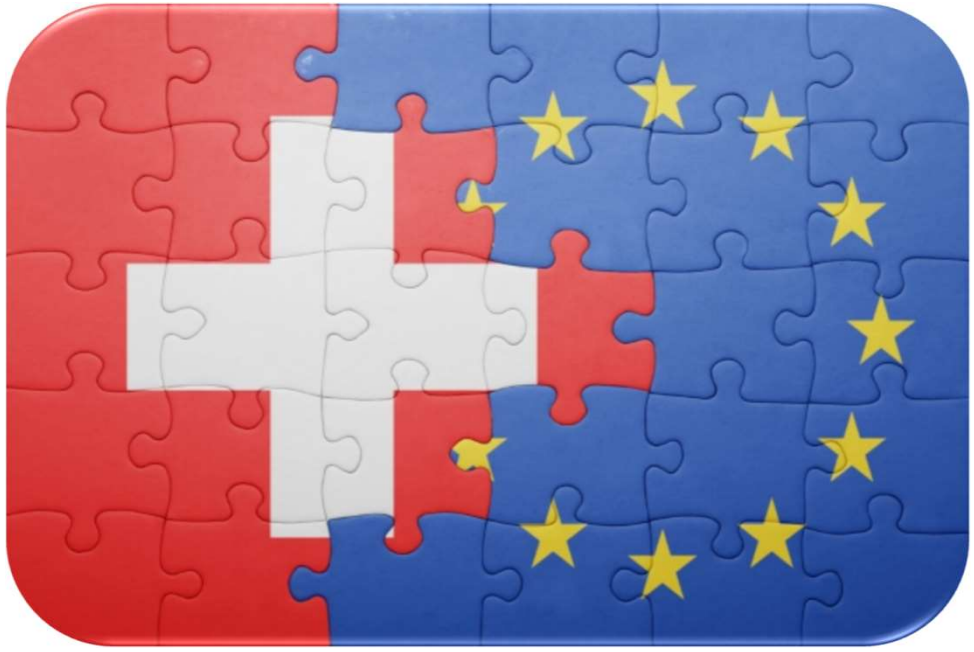


UNITED KINGDOM: England, Scotland, Wales ("Great Britain) and Northern Ireland

- 'Brexit' date: 1 January 2021
- Great Britain creates its own regulatory system – UKCA marking
- Northern Ireland keeps ties to EU and CE marking

Casus Consulting

What happened to the Single Market?



SWITZERLAND

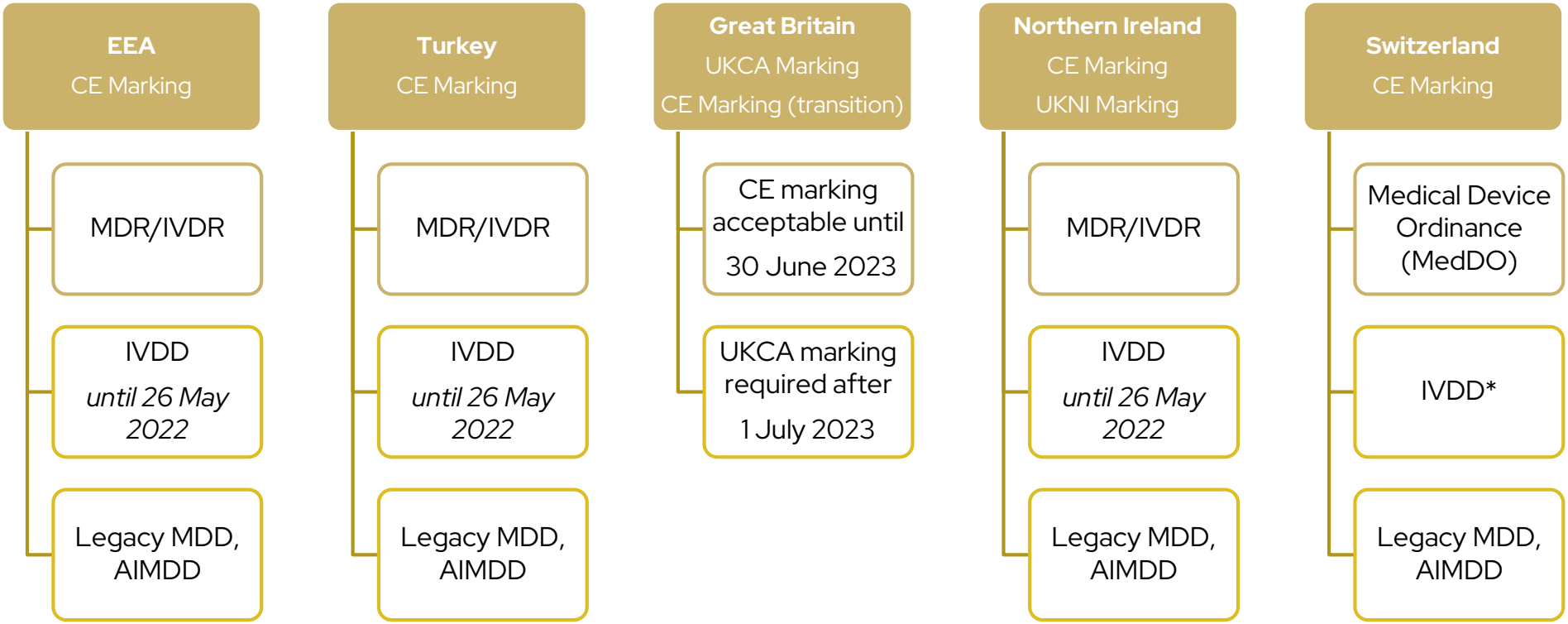
- Access to Single Market dependent upon series of Mutual Recognition Agreements (MRAs)
- Switzerland rejects new EU-CH Institutional Framework Agreement ('InstA')
- EU Commission's response to rejection of InstA: *EU will not update any EU-CH MRAs as regulations change*
- Switzerland suddenly a Third Country for the MDR (26 May 2021)
- No update to MRA as the IVDR date of application approaches (26 May 2022)

Casus Consulting

Requirements

Casus Consulting

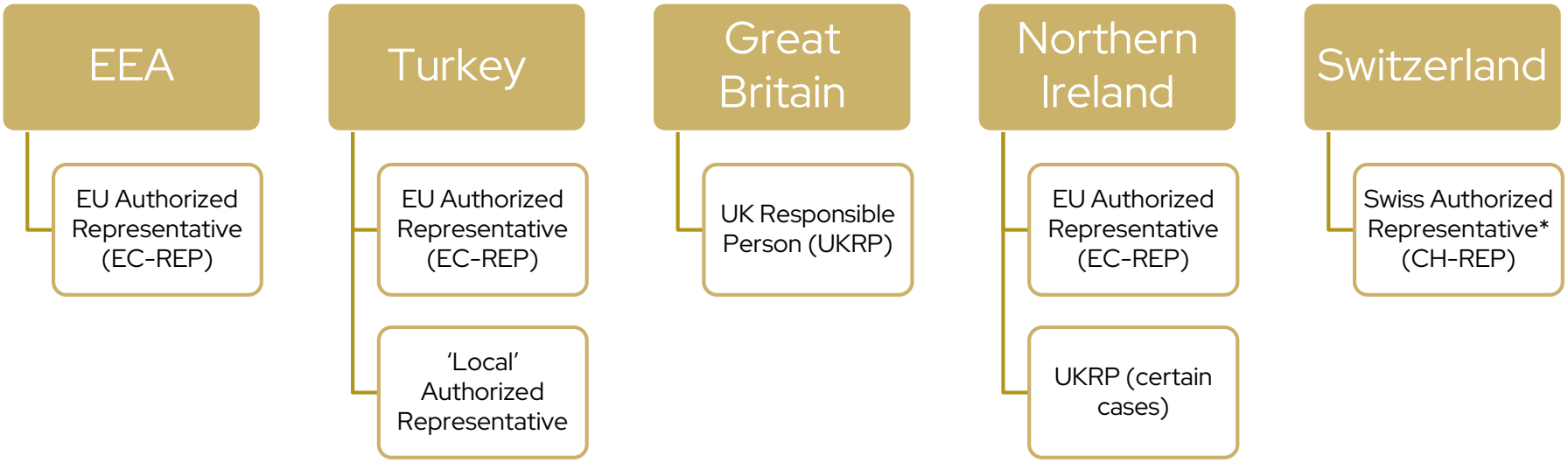
Conformity Assessment



*Switzerland closed consultation re: the IVD Ordinance (IvDO) July 2021, based on the IVDR. To date, the IvDO is pending. The IVDD requirements are currently incorporated into the MedDO.

Casus Consulting

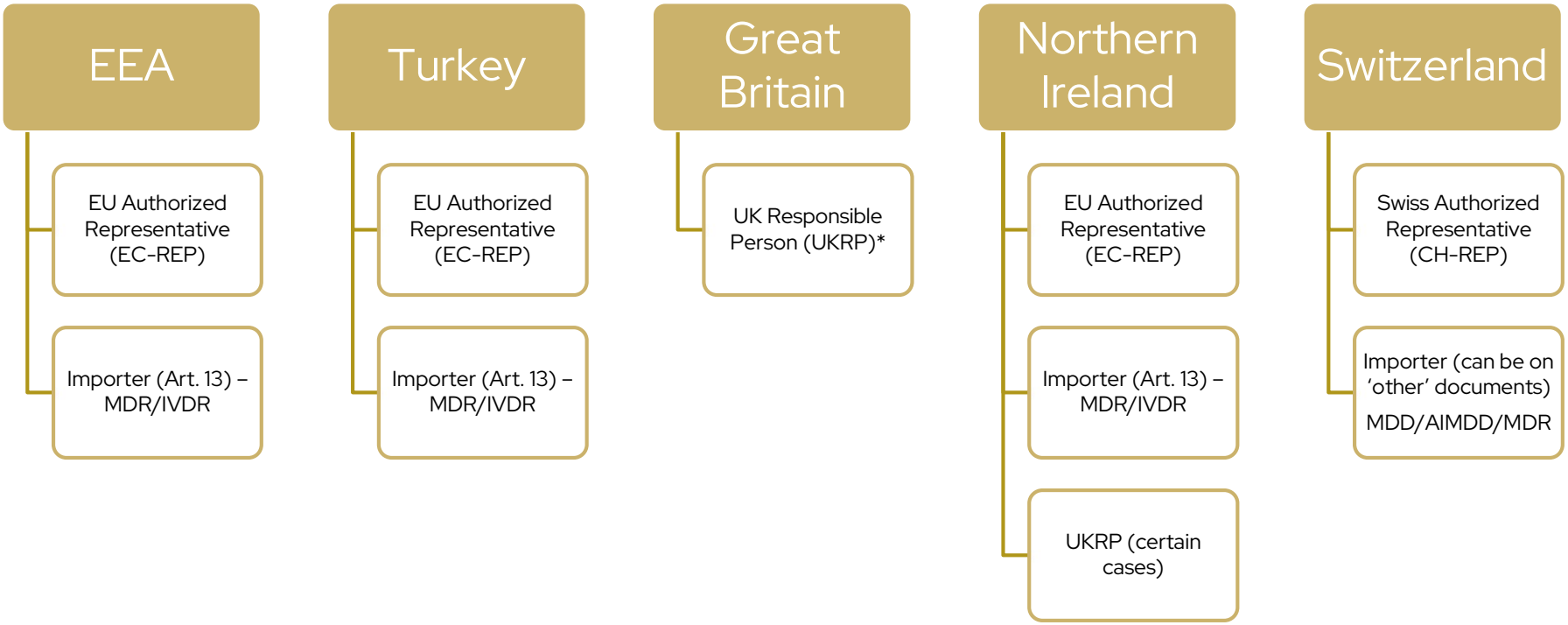
In-country Representative



*Due to a customs treaty between Switzerland and Liechtenstein, manufacturers located in Liechtenstein are not required to appoint a Swiss AR.

Casus Consulting

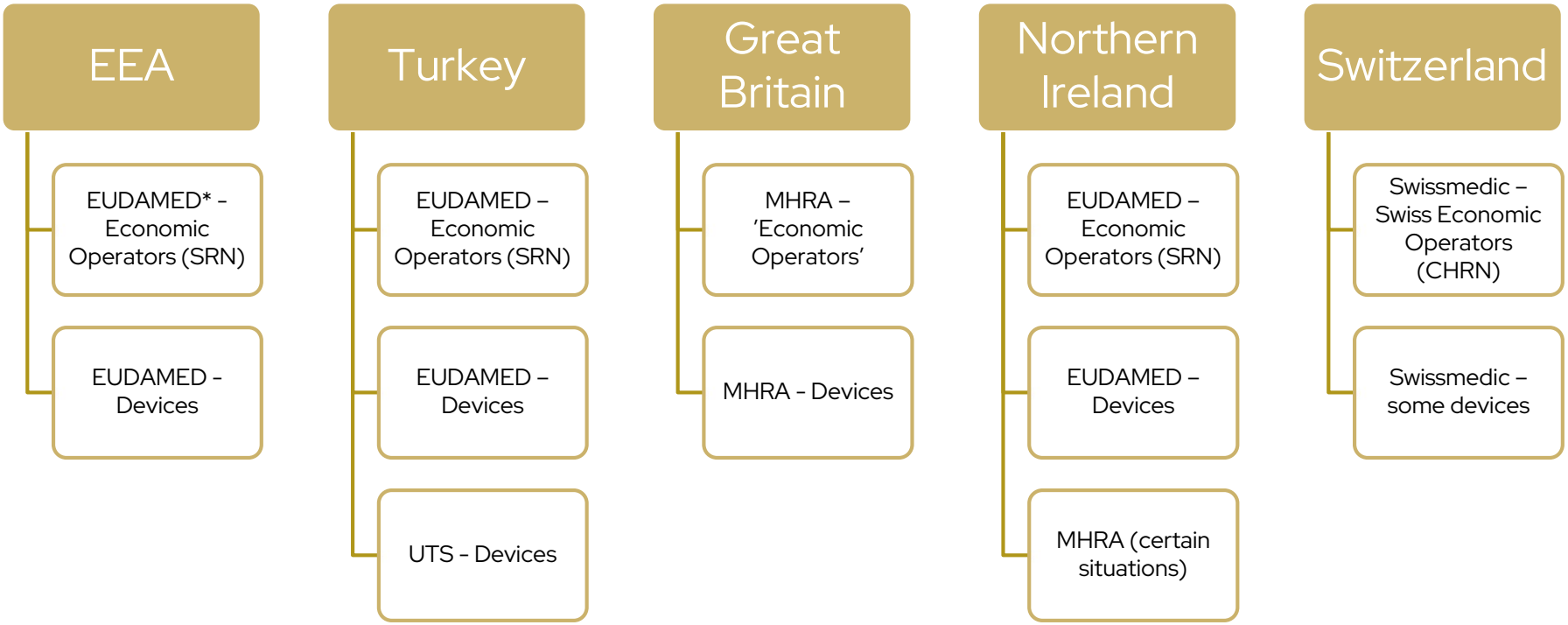
Labeling



*Required if the device has UKCA marking. If using the CE marking transition period allowance, then the UKRP is not needed on labeling.

Casus Consulting

Registration



*EUDAMED has been delayed. Several EUDAMED modules are available for voluntary use. Until EUDAMED is functional, the requirements of the Directives apply, which may require notifying member states individually of devices.

Casus Consulting

Importers

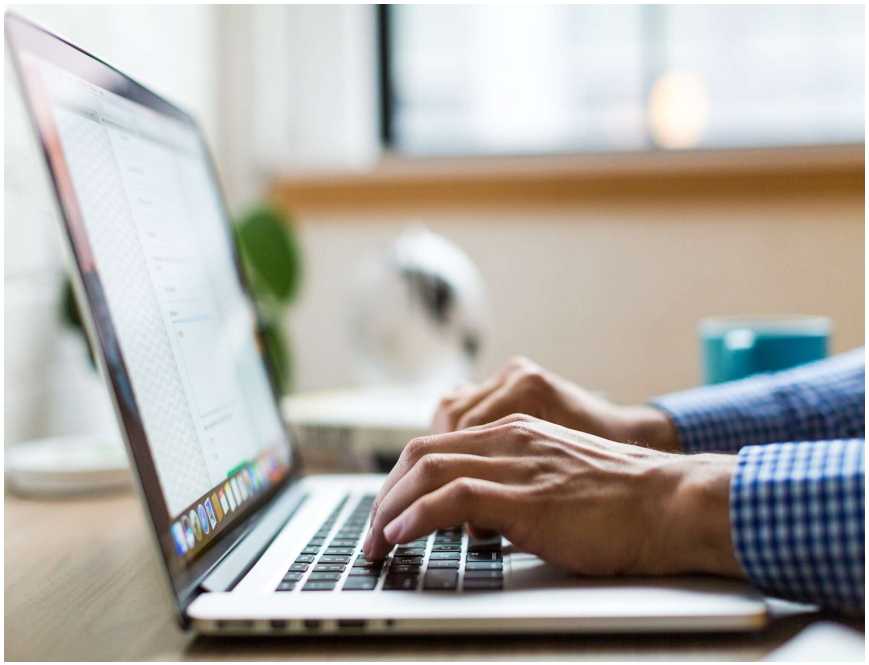
Casus Consulting

More Reading

Important Dates Chart – never again lose track of upcoming European regulatory deadlines

Resources – videos, flowcharts and additional learning

Regulatory Updates – find out what you need to know, and why you need to know it, explained in clear, unfussy language



Still have Questions?

info@casusconsulting.com

The information presented in this document is based on our current understanding of the requirements at the time of publishing and is subject to change.