UK Regulation

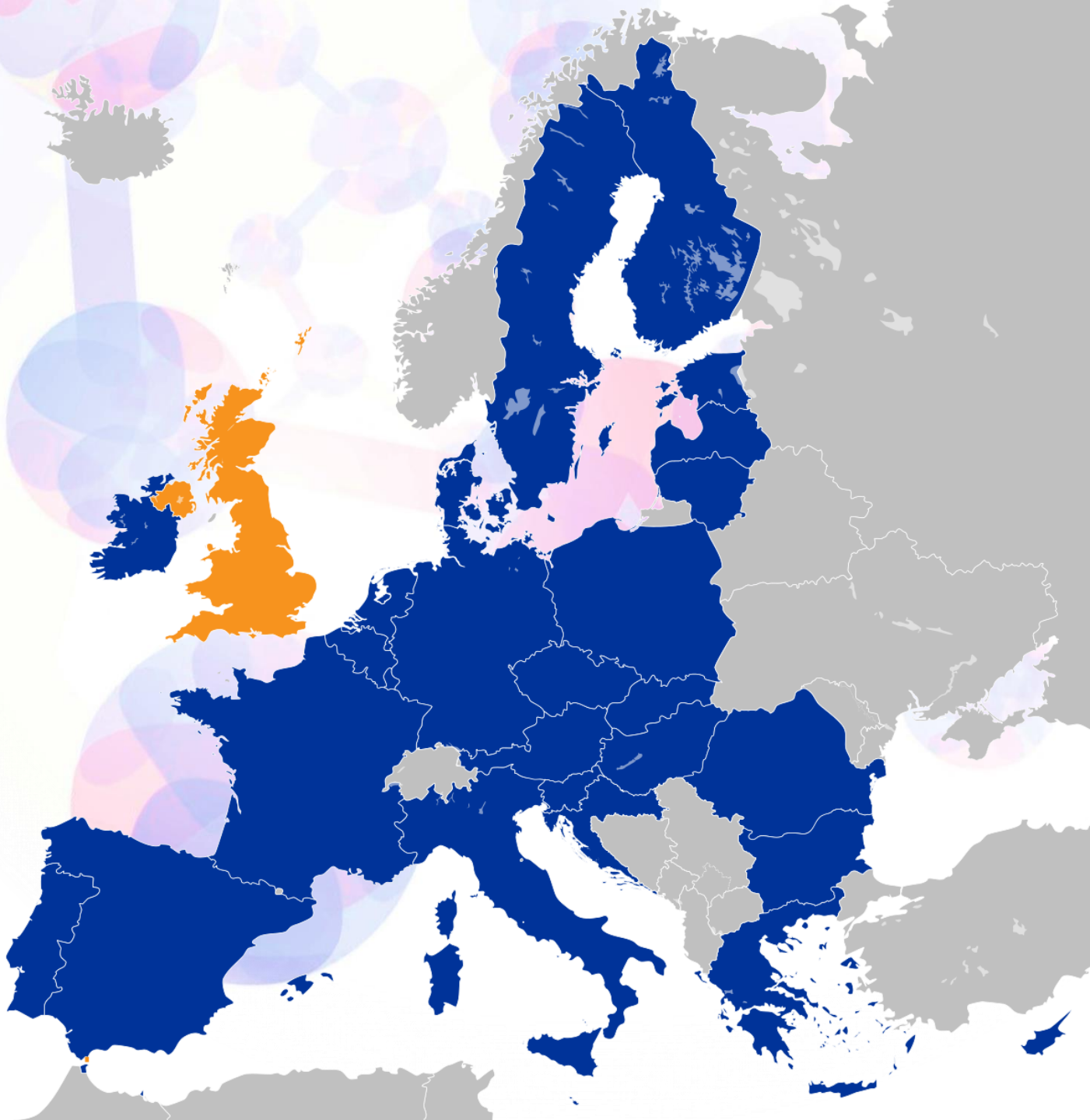
Ashleigh Batchen

BIVDA

British In Vitro Diagnostics Association

Medical Devices Regulations 2002 (MDR)

Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)



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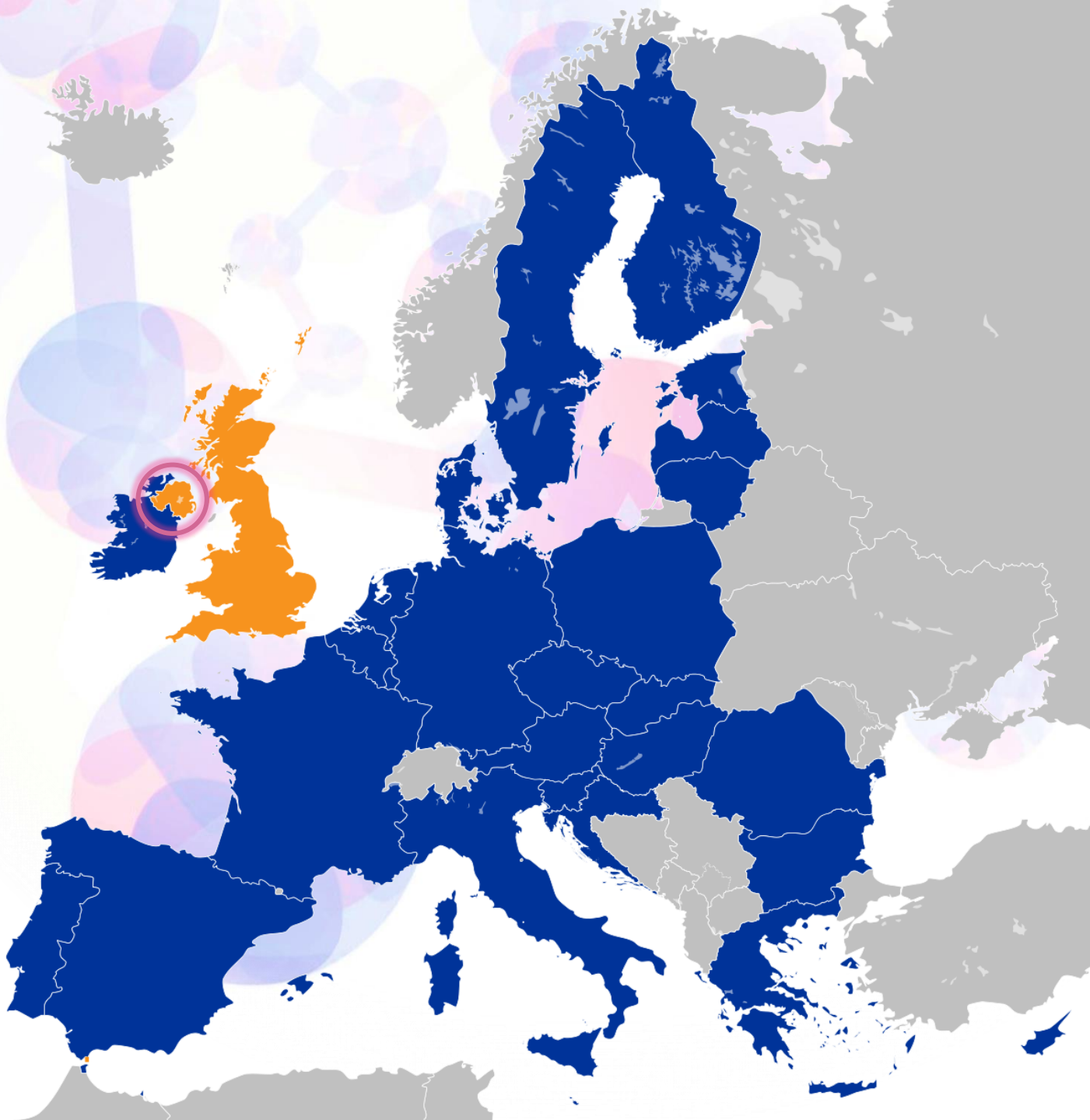


Brexit

- The UK left the EU on 31 January 2020
- This means EU legislation no longer automatically applies in the UK
- However, under the Northern Ireland Protocol, Northern Ireland will continue to implement EU law including the EU IVDR

Great Britain specific requirements

UK Responsible Person

- Required for **non-UK** manufacturers placing devices on the GB market
- Must be established in the UK
- UKRPs should be in place as soon as possible if they are not already
- UKRPs must register IVDs on behalf of the non-UK manufacturer
- A formal contract needs to be in place specifying the agreement and laying out responsibilities
- Will need to be labelled on the product when UKCA label is applied
- BIVDA has a publicly available UKRP register to help manufacturers locate a UKRP

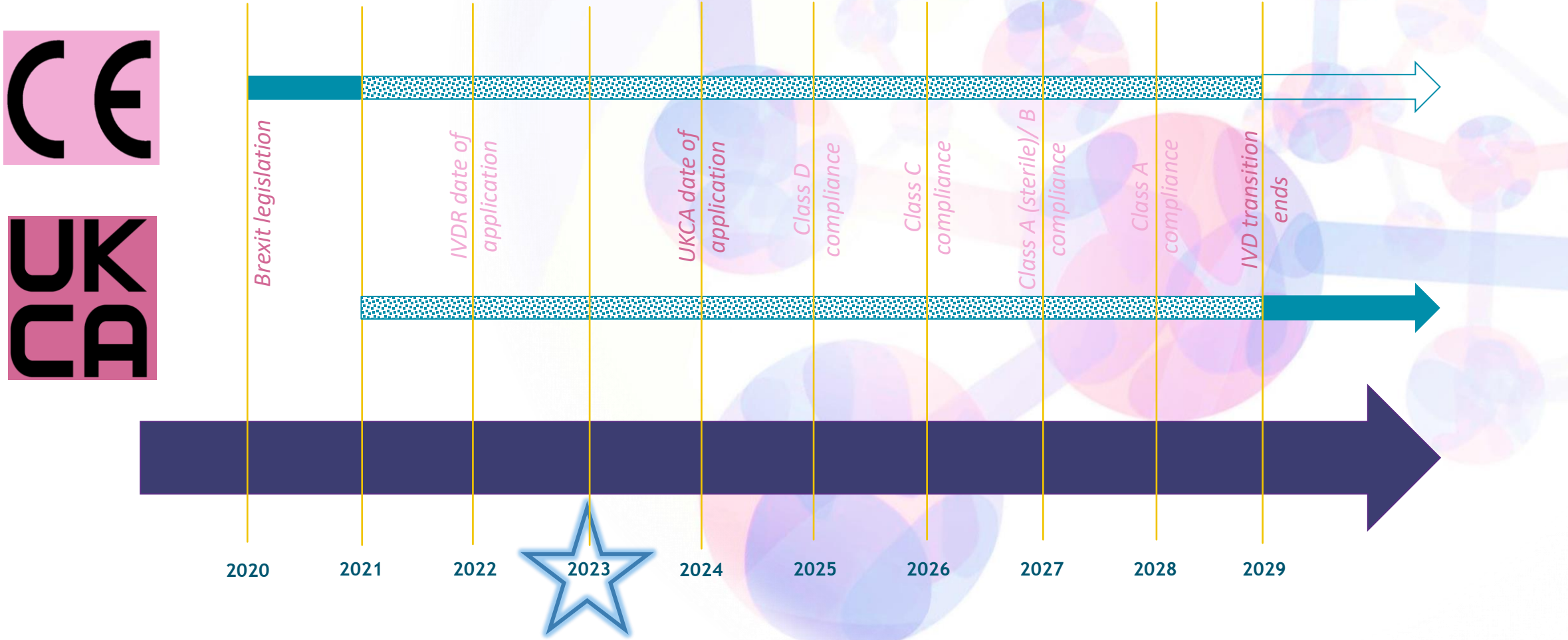
Registration

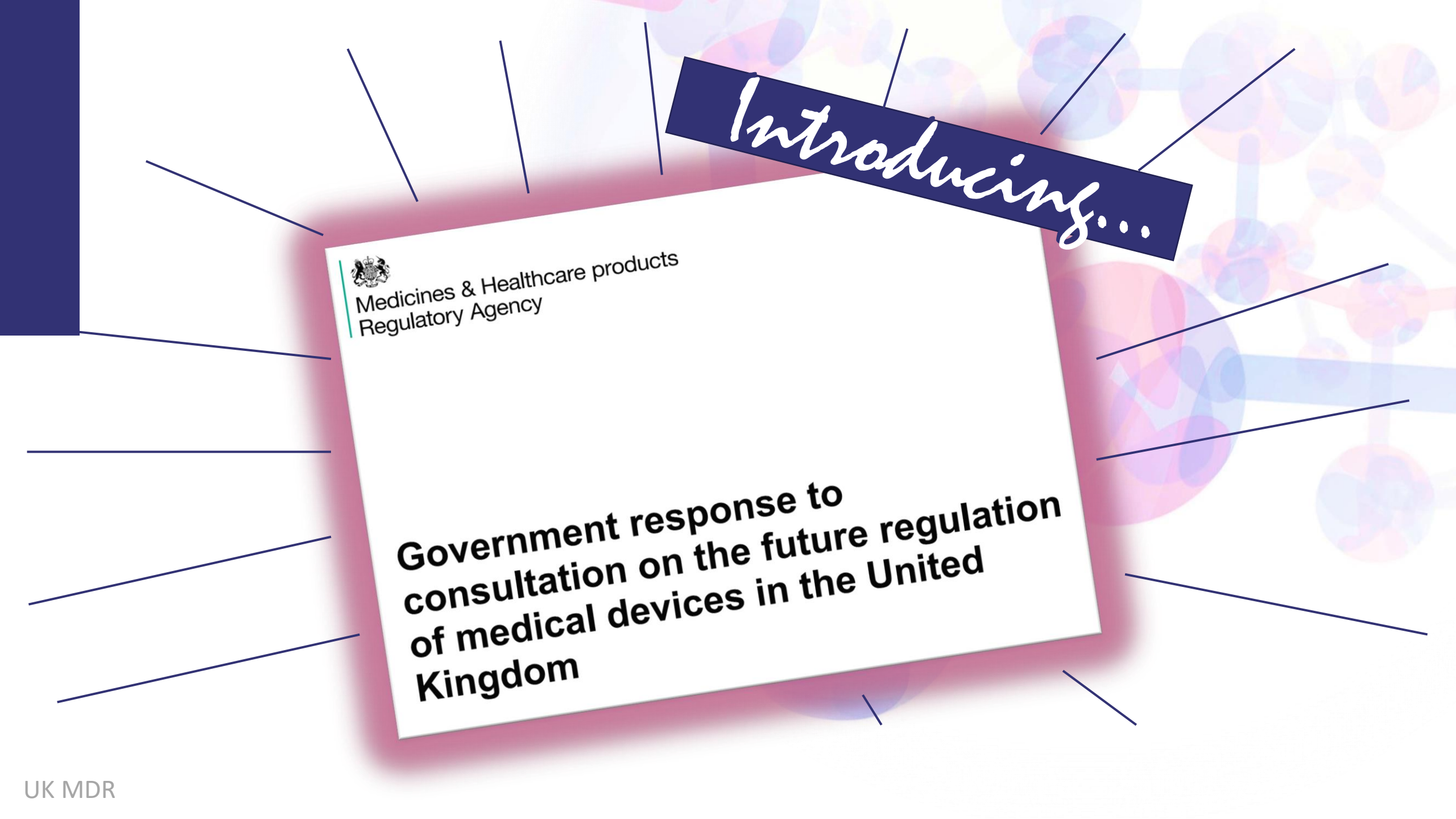
- All IVDs must be registered with MHRA prior to being placed on the market in the UK
- These registrations should be kept up to date by the manufacturer or UKRP
- There is a charge to register (£100)

- It is not an approval system, but some products do go through additional MHRA scrutiny
- Registrations are submitted through the MHRA DORS system

Click picture for link

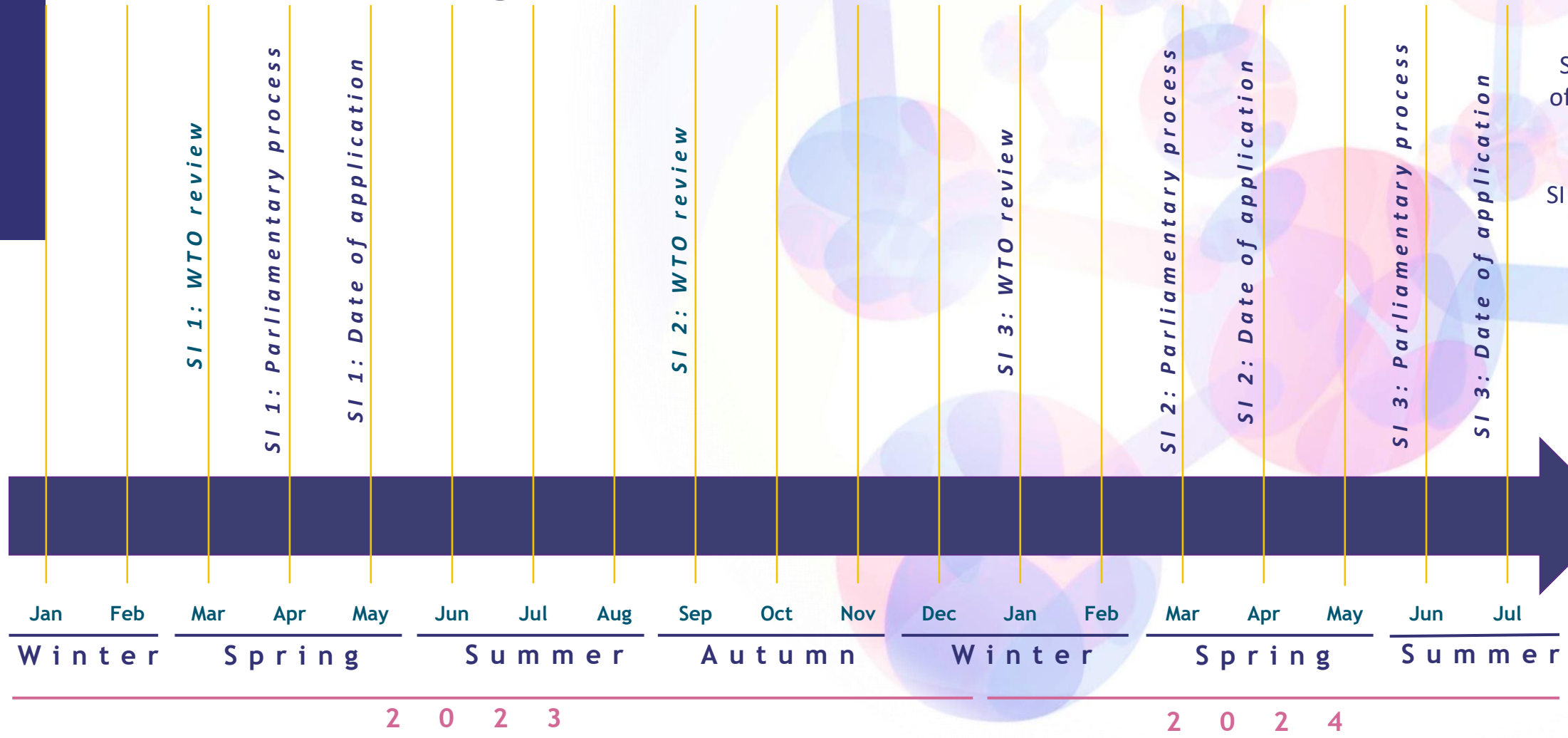
Marking in Great Britain




Introducing...
Medicines & Healthcare products
Regulatory Agency
Government response to
consultation on the future regulation
of medical devices in the United
Kingdom

	UK MDR (IVDs)	UK MDR (medical devices)	EU IVDR	EU MDR
Classification	Class A, Class B, Class C, Class D	Class I, Class IIa, Class IIb, Class III	Class A, Class B, Class C, Class D	Class I, Class IIa, Class IIb, Class III
Registration	Register with MHRA prior to placing on the market in GB	Register with MHRA prior to placing on the market in GB	Register with the competent authority of where the legal manufacturer or authorised representative is based	Register with the competent authority of where the legal manufacturer or authorised representative is based
Conformity assessment body	Approved bodies for Class B, Class C, Class D	Approved bodies for Class IIa, Class IIb, Class III	Notified bodies for Class B, Class C, Class D	Notified bodies for Class IIa, Class IIb, Class III
Relevant timelines	Date of application 1 July 2024, transitional arrangements in place for UKCA and CE marked products	Date of application 1 July 2024, transitional arrangements in place for UKCA and CE marked products	Date of application was 26 May 2022, amended transition timelines implemented dependent on risk class of device	Date of application was 26 May 2021, proposed amendment to transition timelines progressing through EU law proceedings
Marking	UKCA	UKCA	CE	CE
Clinical evidence	Performance evaluation and/or equivalence *(with more stringent requirements)* demonstrating clinical evidence	Clinical evaluation comprised of clinical studies and/or equivalence *(with more stringent requirements)* demonstrating clinical performance	Performance studies and/or equivalence *(with more stringent requirements)* demonstrating analytical performance, clinical performance and scientific validity	Clinical evaluation comprised of clinical studies and/or equivalence *(with more stringent requirements)* demonstrating clinical performance

Estimated legislation timeline

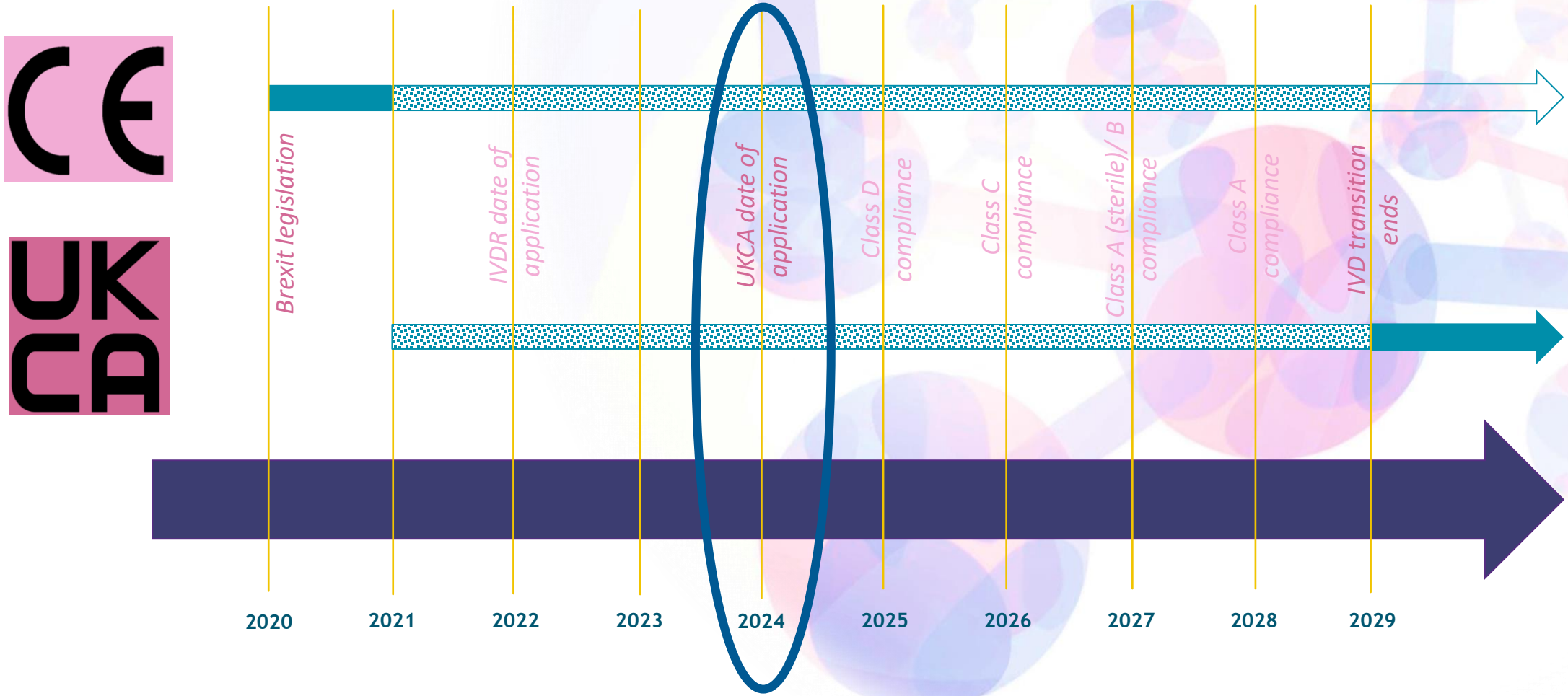


SI 1 = Extension of standstill to Jul 2024

SI 2 = Post-market surveillance requirements

SI 3 = New regulatory framework

Marking in Great Britain



CE certification of conformity to EU IVDD, EU MDD or EU AIMDD

***Must** be **dated prior** to new UKCA date of application*

CE

UKCA certification of conformity to UK MDR

***Must** be **dated prior** to new UKCA date of application*

UKCA

CE certification of conformity to EU IVDR or EU MDR

***Can** be **dated after** new UKCA date of application*

CE

This is also the case for declarations of conformity to these pieces of legislation

CE certification of conformity to EU IVDD, EU MDD or EU AIMDD

*Must be **dated prior** to new UKCA date of application*

Valid until certification expiry or for 3 (MDD)/5 (IVDD) years

UKCA certification of conformity to UK MDR

*Must be **dated prior** to new UKCA date of application*

Valid until certification expiry or for 3 (MDD)/5 (IVDD) years

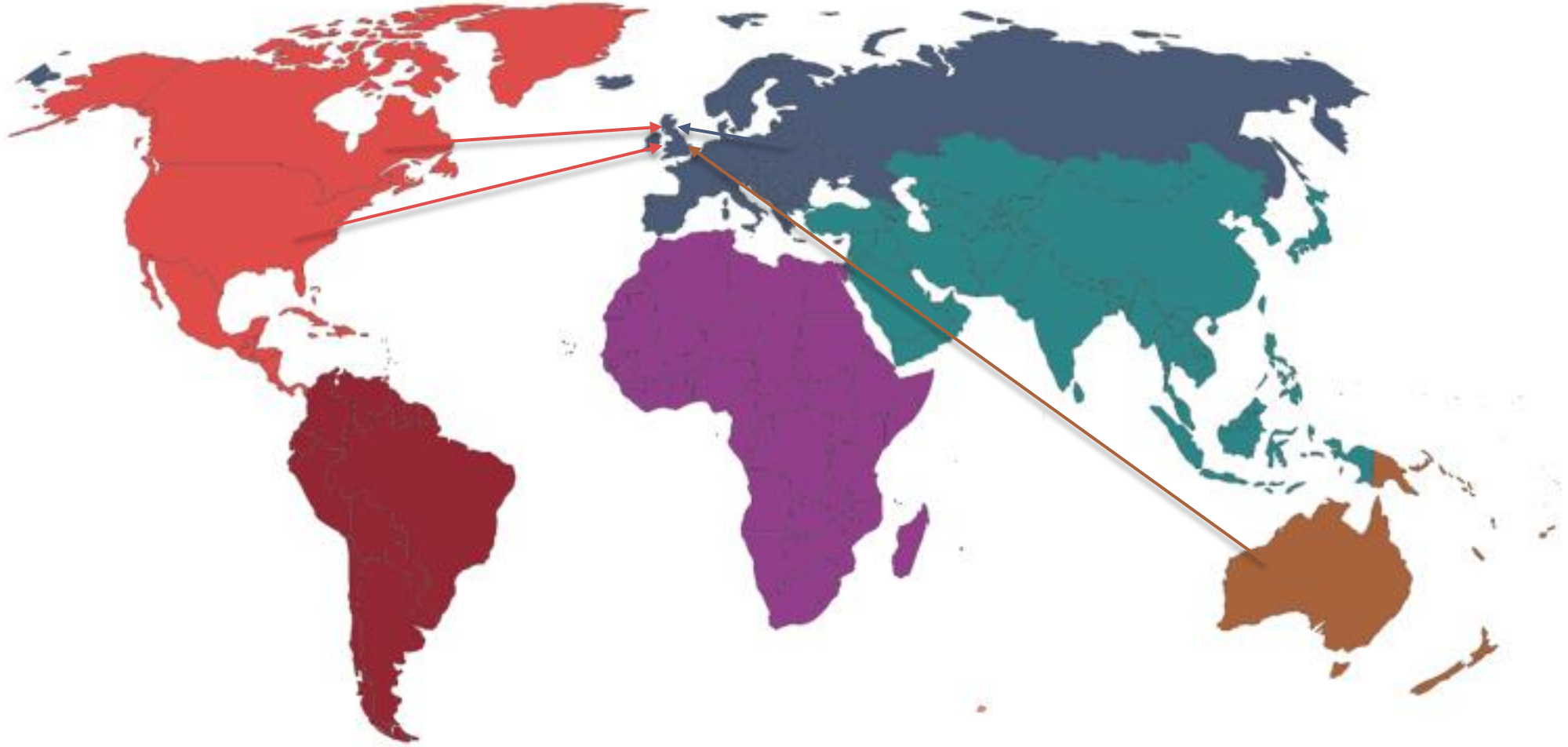
CE certification of conformity to EU IVDR or EU MDR

*Can be **dated after** new UKCA date of application*

Valid until certification expiry or for 5 years

This is also the case for declarations of conformity to these pieces of legislation

Mutual recognition



Environment and sustainability

- Not being put into IVD legislation (yet)
- E-labelling scope being widened, but not beyond software
- Cross-government work ongoing

BIVDA

UK Approved Bodies

DEKRA

On the safe side.

Medical device designation only

bsi.

UL Solutions

SGS

IVD designation only

UK Approved bodies

4 Approved bodies designated…

Several — Actively preparing for designation submission

3 — Post application phase

3 — Post designation audit phase

…More Approved bodies to come

Still to come

- MHRA focus groups
- First drafts of guidance and additional clarity
- The draft regulations
- More approved body designations

Questions?

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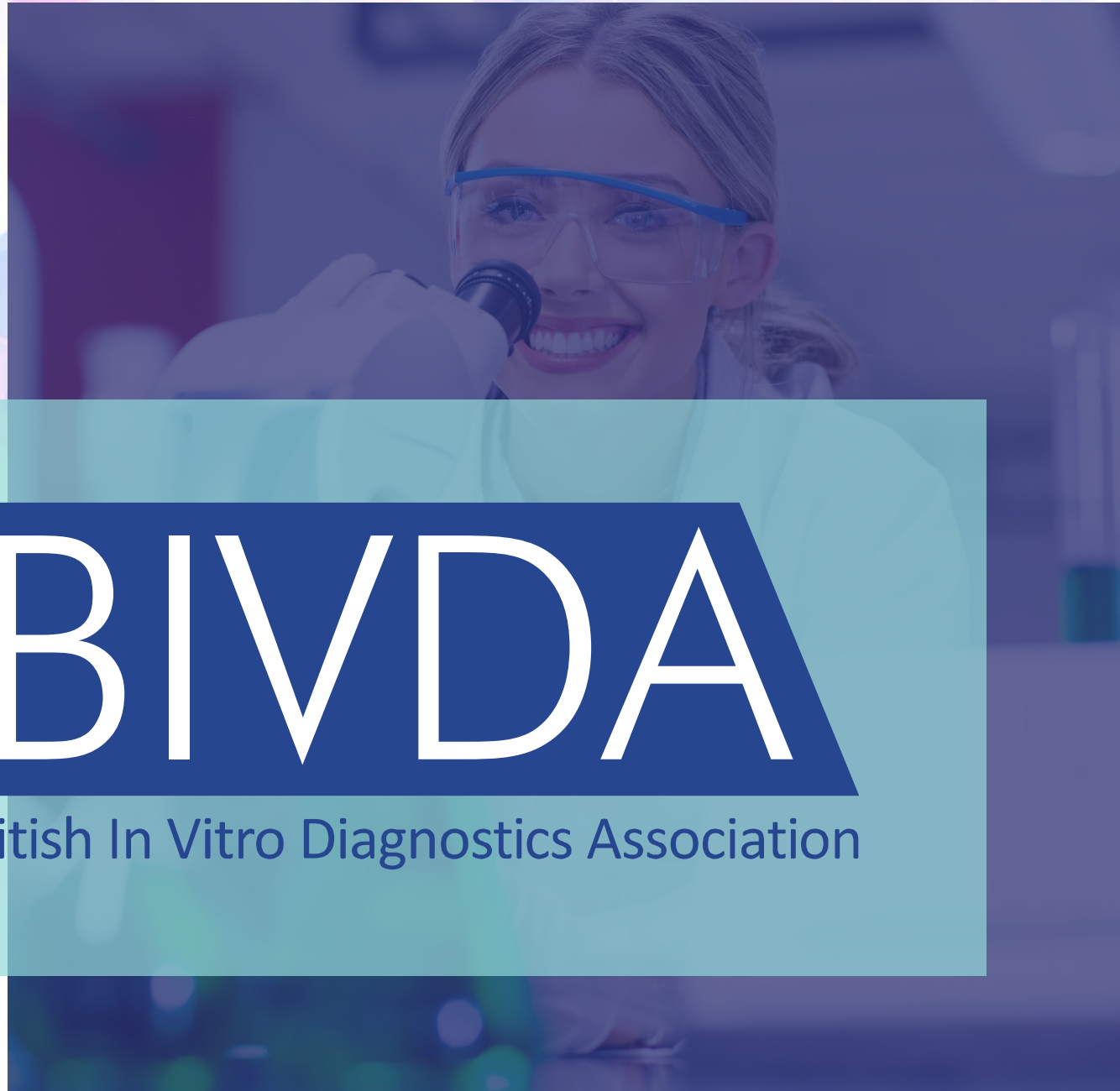

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