MHRA

Regulation of medical devices from 1 January 2021

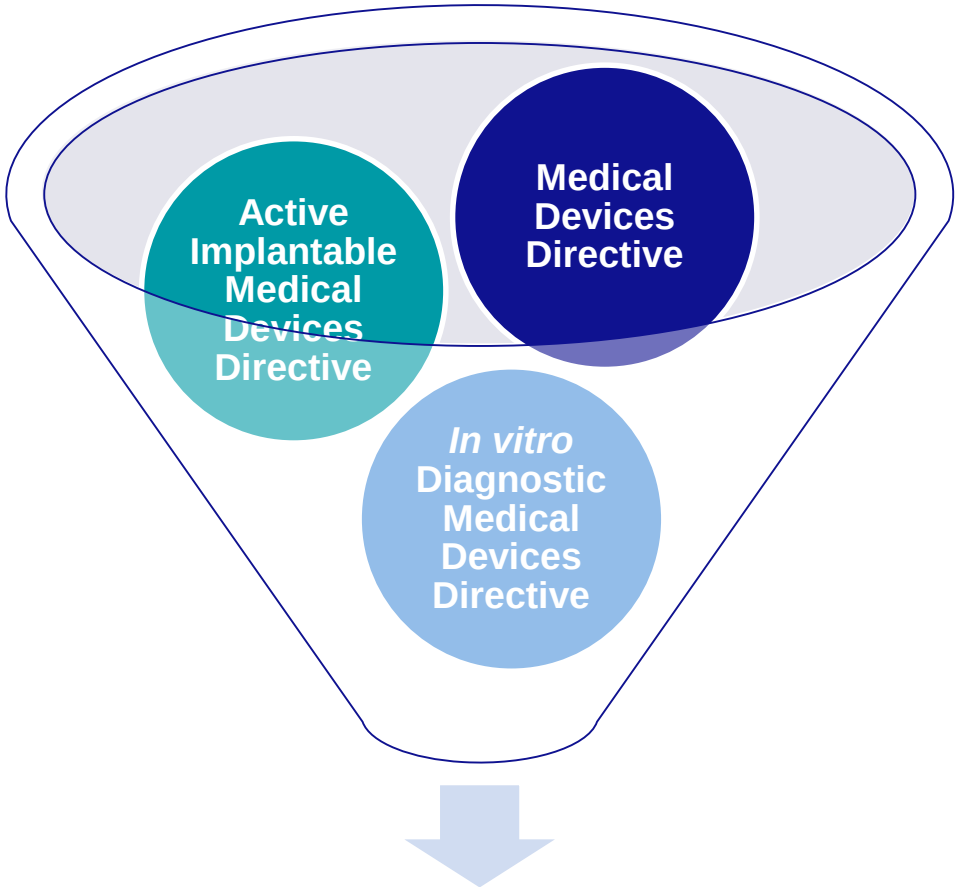
Medicines & Healthcare products Regulatory Agency

Device regulation in Great Britain from 1 January 2021

MDR and IVDR will not apply in Great Britain

MDR	IVDR
• Applies in the EU on 26 May 2021 – outside of transition period	• Applies in the EU on 26 May 2022 – outside of transition period
• Not automatically retained by the EU Withdrawal Agreement Act	• Not automatically retained by the EU Withdrawal Agreement Act

Legislation that will apply in Great Britain

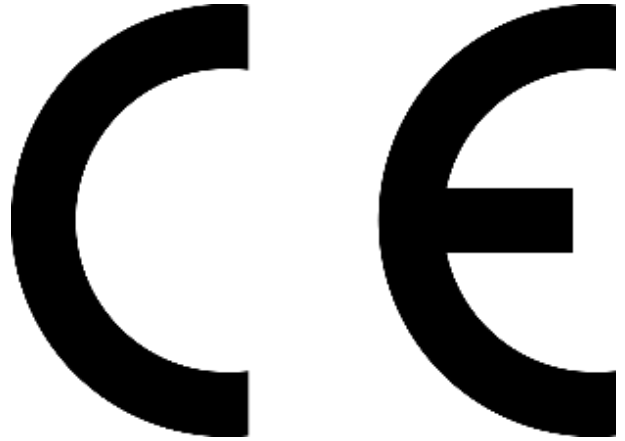


UK Medical Devices Regulations 2002

(in the form they exist on 1 January 2021)

CE marking

- Valid until **30 June 2023**
- Class I and General IVD manufacturers can continue to self-declare
- Existing certificates by UK Notified Bodies valid in GB



UKCA marking

- Valid from 1 January 2021 and **mandatory from 1 July 2023**
- Requirements – MDD, AIMDD, IVDD
- UK Approved Body must be used

Registration of devices in Great Britain

Registration from	Medical devices to be registered*	IVDs to be registered
1 May 2021	• Class III medical devices • Class IIb implantable medical devices • Active implantable medical devices	• IVD List A products
1 September 2021	• Class IIb non-implantable medical devices • Class IIa medical devices	• IVD List B products • Self-test IVDs
1 January 2022**	• Class I medical devices	• General IVDs

*Custom-made devices to be registered in line with the risk class of the device

**Applies only to devices that are not already required to be registered

UK Responsible Persons – GB requirements

UK Responsible Persons
• Required for **non-UK** manufacturers placing devices on the GB market
• Must be established in the UK
• We recommend that UK RPs are in place, where required, by **1 January 2021**
• UK RPs must register devices on behalf of the non-UK manufacturers in line with registration grace periods (from 1 May 2021, 1 September 2021 or 1 January 2022 depending on device class)

UK Responsible Person – responsibilities

Ensure that the declaration of conformity and technical documentation have been drawn up

Keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate

In response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device

Provide samples of a device to the MHRA or allow the MHRA access to the device where the UK responsible person has samples or access, where they do not have access or samples, forward to the manufacturer any request from the MHRA for samples or access

Cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices

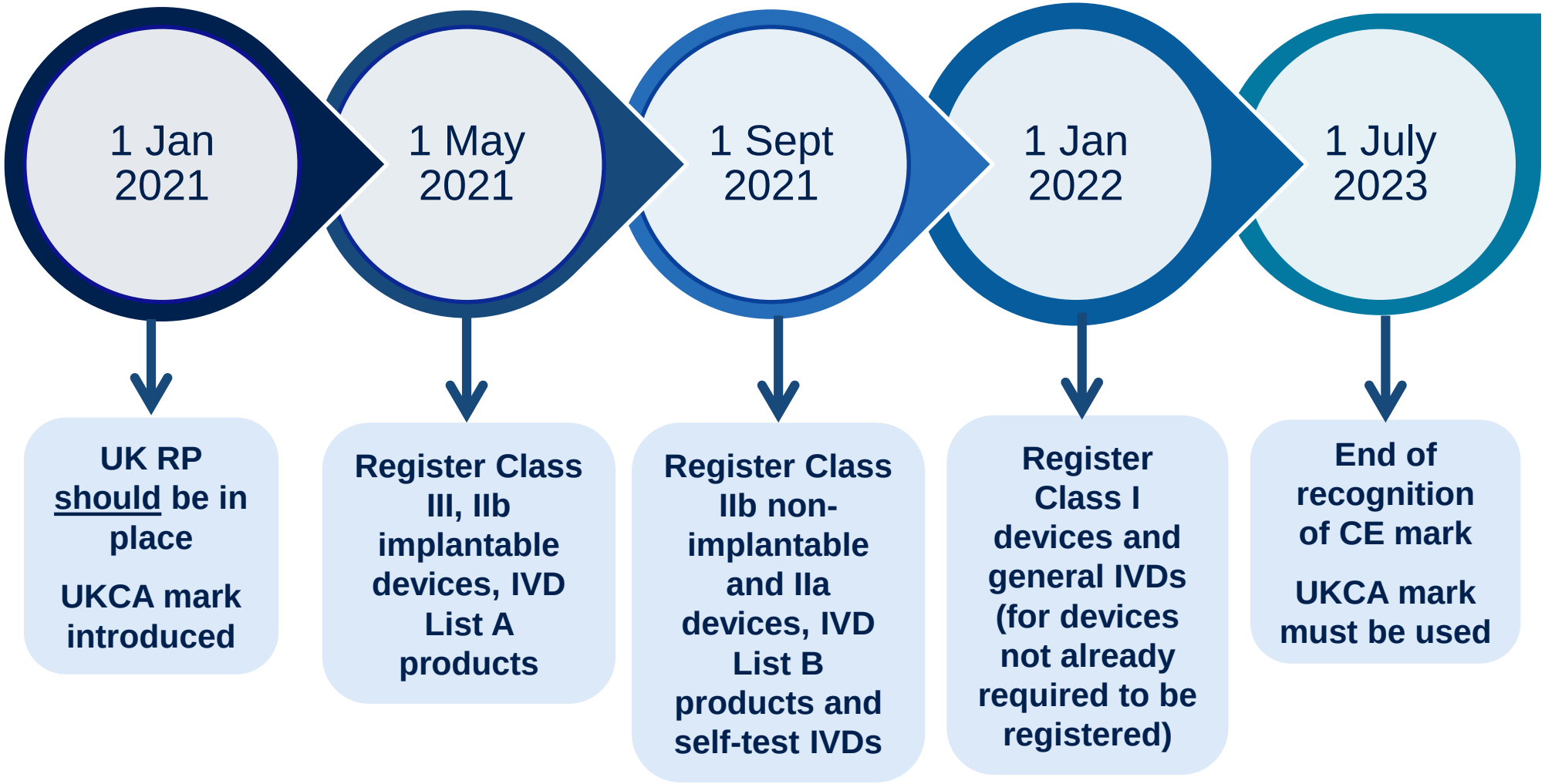
Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents

Terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the MHRA

UK Notified Bodies

- UK Notified Bodies will become ‘UK Approved Bodies’ from January 2021
- **Will not** be able to conduct conformity assessment for **EU** market
- **Will** be able to conduct conformity assessment for **UKCA** mark

Timeline overview and key actions: GB



Device regulation in Northern Ireland from 1 January 2021

Northern Ireland Protocol

- In October 2019, the NI Protocol was agreed as part of the UK's departure from the EU (the Withdrawal Agreement).
- NI Protocol establishes a single regulatory zone on the island of Ireland.
- Northern Ireland will have access to the EU Single Market and requires NI to continue to align with certain EU rules.
- UK government has made commitments on unfettered access – so NI businesses will have access to the rest of UK market.

MDR and IVDR in Northern Ireland

MDR	IVDR
• Applies in the EU on 26 May 2021 – outside of transition period	• Applies in the EU on 26 May 2022 – outside of transition period
• Will fully apply in Northern Ireland under the NI Protocol	• Will fully apply in Northern Ireland under the NI Protocol

CE marking and UKNI marking

- CE marking will continue to be needed in NI.
- Manufacturers can continue to self-certify devices to EU standards where relevant.
- Where third party assessment is required:
  - If an EU Notified Body is used, a CE marking must be applied – will be valid for NI and the EU.
  - If a UK Notified Body is used, a UKNI marking must accompany, but not replace, the CE marking – will be valid for NI market only.
- The UKCA mark alone will not be valid for the NI market. Dual marking will be accepted.

Registration of devices in Northern Ireland

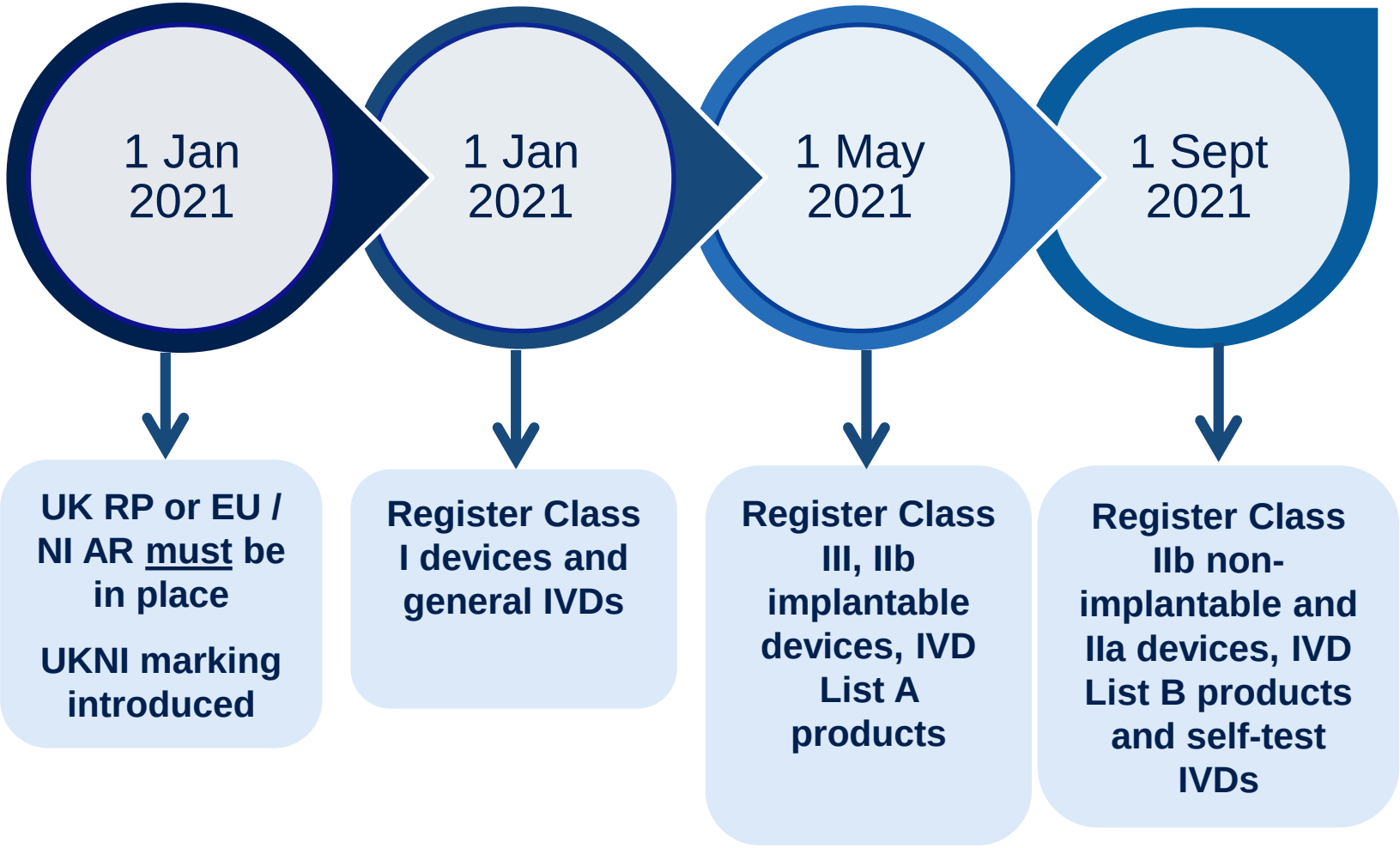
Registration from	Medical devices to be registered	IVDs to be registered
1 January 2021	• Class I medical devices	• General IVDs
1 May 2021	• Class III medical devices • Class IIb implantable medical devices • Active implantable medical devices	• IVD List A products
1 September 2021	• Class IIb non-implantable medical devices • Class IIa medical devices	• IVD List B products • Self-test IVDs

Devices that are registered in Northern Ireland by Northern Ireland manufacturers will be accepted on the GB market and will not need any further registration with the MHRA

UK Responsible Persons and Authorised Representatives – NI requirements

UK Responsible Persons	Authorised Representatives
• Required for **EU** manufacturers of devices other than Class Is and General IVDs	• Required for **GB** manufacturers of devices of all classes and **third country** manufacturers of certain device classes
• Required for **third country** manufacturers of devices other than Class Is and General IVDs *unless an NI AR has been appointed*	• **NI AR:** all device classes must be registered **EU AR:** all device classes other than Class I devices, custom made devices and General IVDs must be registered
• Will need to be in place by **1 January 2021**	• Will need to be in place by **1 January 2021**
• Will register devices on behalf of the non-UK manufacturers in line with grace periods	• AR will register devices on behalf of third country manufacturers in line with grace periods • GB manufacturers will register own devices

Timeline overview and key actions: NI



Contact us

Devices.Regulatory@mhra.gov.uk

Published guidance can be found at:
www.gov.uk/government/collections/mhra-post-transition-period-information

Guidance on the UKCA mark can be found at:
www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021

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