Ortho Clinical Diagnostics

2021 AMDM Annual Virtual IVD Regulatory Meeting

The UKCA mark and Impacts for IVD Manufacturers

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Disclaimer

- The opinions and/or proposals reflected in this presentation are solely those of the author.
- Whilst based on discussion taking place in multiple groups, the content cannot be considered as a statement from a specific company or organisation.

Agenda

1	BREXIT
2	What is the United Kingdom and current legislation? Requirements for Great Britain and Northern Ireland
3	Registrations (Grace periods) UK Responsible Person
4	UKCA and UKNI marking
5	The Future - Development of UKCA mark regulation

Brexit

- **On the 1st January 2021 the United Kingdom became a 'third country' from an EU perspective:**
  - No Single Market
  - No Customs Union
- **The EU has clear and well understood rules for third countries:**
  - Products placed on the EU market from UK are imported and therefore require an EU "Importer".
  - UK Manufacturers require an Authorised Representative within the EU – labelling and mandate required

What Makes Up the UK?

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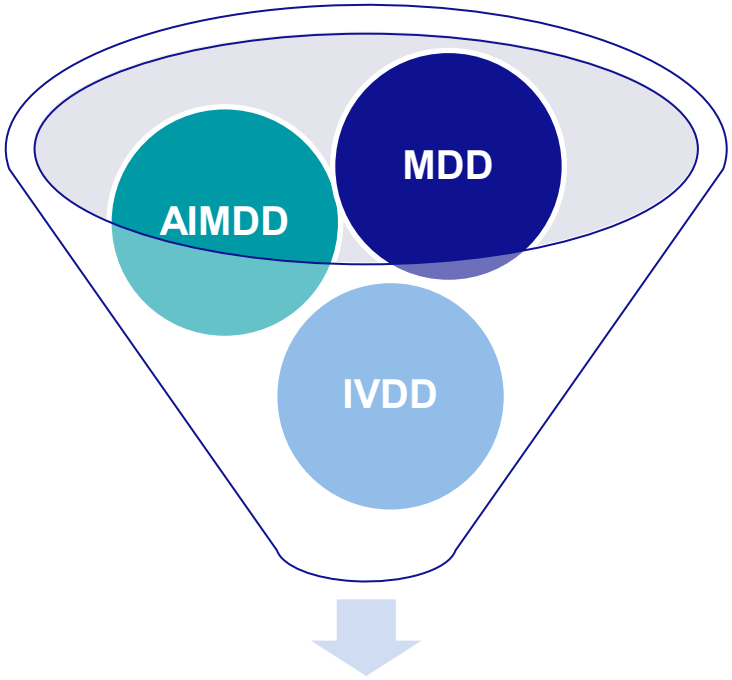
- England, Wales and Scotland together are called Great Britain
- The United Kingdom consists of Great Britain and Northern Ireland
- The Isle of Man and the Channel Islands are the Crown Dependencies; they are not part of the UK but they follow most of UK legislation
- Ireland consists of the Irish Republic and Northern Ireland (note: 'Unionists' want to keep it that way).

Legalisation in Great Britain and Northern Ireland

Legislation in Great Britain



UK Medical Devices Regulations (S.I. 2002/618)

New: Medicines and Medical Devices Act 2021 (M&MDA) – published February 2021

IVDR

- Date of Application in the EU on 26 May 2022 – outside of transition period
- Not automatically retained by the EU Withdrawal Agreement Act

United Kingdom - Which laws apply?

– New: Medicines and Medical Devices Act 2021 (M&MDA):
  - Powers to pass multiple regulations
  - New liability / enforcement provisions
  - **Powers to establish UK-wide device information systems
  - **Independent Patient Safety Commissioner
  - Advisory Committee re devices
– **Cumberlege Review (Jul 2020):
  - Product-specific redress schemes

Medical Devices Regulations 2002 (as amended)

– Implement EU legislation in NI
– Apply EU law @ 31 Dec 2020 as 'retained law' in GB
– New UK registration requirements for:
  - Manufacturer, UK Responsible Person
  - Medical devices / IVDs

Great Britain Requirements

Great Britain

- ✓UKCA mandatory from 1 Jul 2023
- ✓UKCA declared to EU law @ 31 Dec 2020 from 1 Jan 2021
- ✓CE Mark accepted till 30 Jun 2023
- ✓EU-27 NB certificates valid till 30 Jun 2023
- ✓UK Approved Bodies (UKABs) from 1 Jan 2021

- **UK device registration requirements ('grace periods' apply) – see slide 13**
- **UK Responsible Person – see slide 14**

MHRA Guidance issued 31 Dec 2020 summarises changes:

- Regulating medical devices in the UK - GOV.UK (www.gov.uk)
- Additional Guidance on registration: Register medical devices to place on the market - GOV.UK (www.gov.uk)

Northern Ireland Requirements

Northern Ireland (NI)

NI: continued requirement for CE Mark.

- EU IVDR will apply in NI
- A product shipped from GB to NI is an “imported product” into the EU.

CE

Grace Periods and UK Responsible Person

Grace Periods - Registration of devices in Great Britain

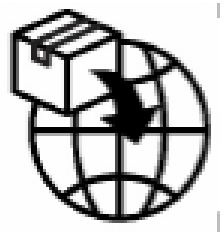
Device Category	Registration deadline ('grace periods')
• Annex II - List A IVDs	30 April 2021
• Annex II - List B IVDs • Self-test IVDs	31 August 2021
• General IVDs	• 31 December 2021 • No 'grace period' for Class I or general IVDs already required to register (UK based manufacturers)
Note: deadline for UKRP registration aligned with product registration deadlines	

UK Responsible Person (UKRP)

1. UK RPs must register devices on behalf of the non-UK manufacturers in line with registration grace periods.
2. Must register themselves, their manufacturer, their devices and their importer(s) with MHRA.
3. Role similar to the role of the Authorized Representative in the EU.
4. Responsibilities regarding verifying compliance of devices, reporting, cooperation with MHRA, keeping documents on file etc.
5. Must be established (legal entity) in the UK.
6. UK RPs should be in place before your device is placed on the market.
7. Can be combined with role of importer, but not required.

The UKRP was mandatory from 1st January 2021

UK Importer



1. Role similar to the role of the importer in the EU
2. Legal person based in the UK
3. Can be combined with role of UKRP, but not required
4. The UKRP will ask the manufacturer to verify the importer
5. Recommended for the manufacturer to specifically appoint an importer
6. Must be registered by the UKRP at the MHRA

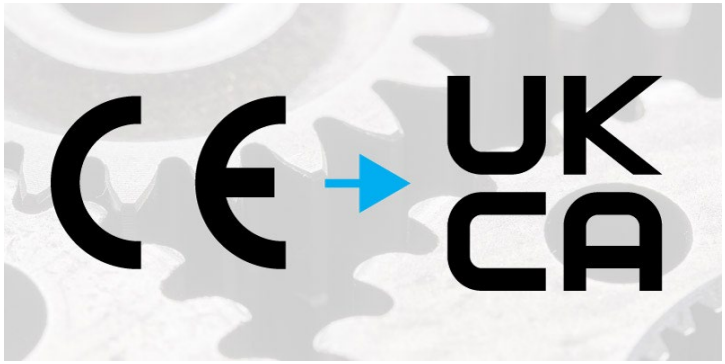
The Importer was mandatory from 1st January 2021

Registrations

1. Registrations can only be done by the UK manufacturer or UKRP
2. UKRP must register themselves, their manufacturer, the importer(s) and the devices
3. Registration via ‘application to DORS system (Device On-line Registration System)
4. Application can have all economic operators listed and multiple products
5. Spreadsheets for mass data dumps available
6. ‘Devices’ are linked to GMDN codes, max 100 devices per application

UKCA and UKNI Conformity Assessment Marking

UKCA marking



1. Replaces CE-marking
2. Effective from 1st January 2021, but will be mandatory from 1st July 2023.
3. UKCA certification by UK Approved Bodies (UKAB)
4. At this moment only three UKAB: UL (UK), SGS and BSI (others may follow)
5. UL (UK), SGS and BSI will keep their numbers (#0843, #0120 and #0086 respectively)
6. At this moment Medical Devices Regulations 2002 apply (=Directives)
7. UKCA / CE dual marking is accepted after 1st January 2021
8. UKCA marking requires the UKRP on the labelling, and the importer on the device, the label or a document accompanying the device.
9. New legislation is in the making, expected to stay close to IVDR – see later slides

Northern Ireland Protocol

- October 2019 – the **NI Protocol** was agreed
- Northern Ireland will have access to the **EU Single Market**
- UK Government has made commitments on **unfettered access**

UKNI marking

1. You never apply the UKNI marking on its own - it always accompanies an EU conformity marking (CE mark).

2. UKNI is not recognized on the EU Market.

3. The UKNI marking is sometimes referred to as the UK(NI) mark or the UK(NI) indication, including in Article 7(3) of the Northern Ireland Protocol. These are the same marking.

Link: https://www.gov.uk/guidance/using-the-ukni-marking-from-1-january-2021

Accepted markings for different markets

Note: Your goods may require different markings for different markets. The table below illustrates the accepted markings on each market.

	Type of good (see list of product areas below)	Accepted marking or combination of markings*
Placing IVD products on the market in Great Britain	Manufactured goods being placed on the GB market until the end of June 2023	CE or UKCA
	Manufactured goods placed on the GB market from 1 July 2023	UKCA
Placing IVD products the market in Northern Ireland	Manufactured goods being placed on the market in NI using an EU conformity assessment body	CE
	Manufactured goods being placed on the market in NI using a UK-based body	CE and UKNI
Placing IVD products on the EU market	Manufactured goods being placed on the EU market	CE

The Future - UKCA Marking

Development of UKCA Mark Policy

Policy development – Q1/Q2 2021

Formal consultation on draft UKCA mark legislation (Q2/Q3 2021)

Responses to consultation (Q3/Q4 2021)

Final legislation published (Q4 2021 / Q1 2022)

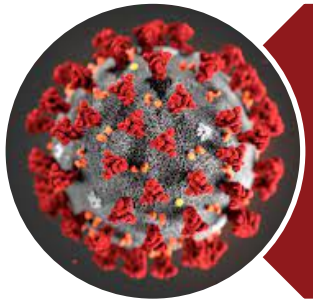
Mandatory application date of 1 July 2023?

Have stressed the Industry concern with the application date

Future UK Regulatory Framework for IVDs

Focus of regulation will continue to be patient safety but proportionate to the risk.

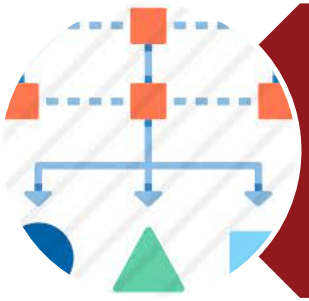
The regulations will incorporate much of the substance of EU IVDR



Experience of COVID-19 – Industry working more closely with NHS to establish early stage systematic clinical and patient data for higher risk devices.

Future UK Regulatory Framework for IVDs

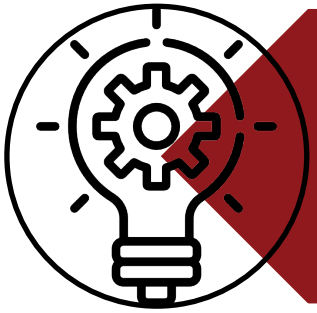
Will consider international standards, best practice and global harmonisation (MDSAP).



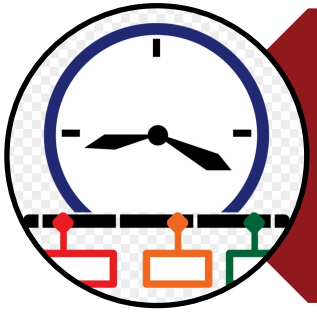
Likely to adopt the same classification system as the EU IVDR.

Emphasis on Clinical Evidence, but potentially more proportionate to the risk of the device.

Future UK Regulatory Framework for IVDs



Position the UK to be the “best” in innovative technologies – the “Go-To” for Development.



Working in partnership with Industry to encourage global / international access through quicker access to UK market.

Focus on innovative digital technology and appropriate regulation.

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