"An Update on the Regulatory Landscape in the UK One Year into Brexit"

2022-05-02

QAdvis

Before We Start…

- The webinar is one hour in total, appr. 30-40 min. presentation and remaining time for Q&A
- Post questions about the webinar topics in the Q&A window
- Other stuff, technical issues, etc, in the chat window
- Cameras and microphones are turned off/muted by host
- The webinar is recorded

Disclaimer

Please note that, any views given by us on the interpretation of the legislation represent our best judgement at the time, based on the information available (and our current understanding of the products). Such views are not meant to be a definitive statement of law, which may only be given by the courts.

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Per Sundström – Background

- 20+ years in SW Development
- 25+ years in Medical Device SW
- Worked as R&D Manager, Project manager, Startup CEO, Chairman of the board
- Participated in ~5 audits, FDA, MDD, etc.
- Former member of ISO TC215/IEC SC62A Joint Workgroup 7 with focus on IEC 80001
- Head of Sales for QAdvis AB
- Responsible for QAdvis EAR and UKRP business

An Update on the Regulatory Landscape…

1	**Background**
2	UKCA Marking
3	MHRA Registration
4	UK Responsible Person (UKRP)
5	UKRP Services by QAdvis
6	Advice for Manufacturers

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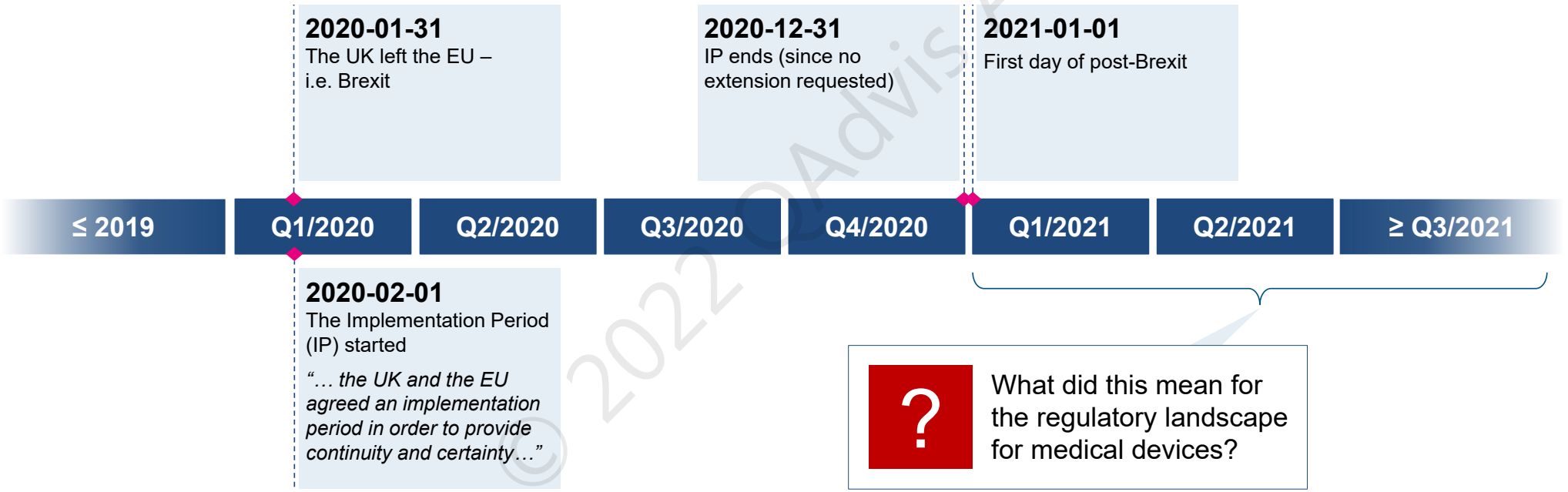
Brexit Timeline



Changes To the Medical Devices Regulations 2002 (UK MDR 2002)

- Introduction of a new marking system – “UK Conformity Assessed” (UKCA) marking
- Introduction of the role “UK Responsible Person” (UKRP)

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UKRP and UKCA Timeline

2021-01-01
Non-UK Medical Device manufacturers must designate a UKRP

2021-08-31
The following devices must be registered with MHRA:
- Class IIb, IIa
- IVD List B
- Self-test IVD

- Devices must be registered before placed on the market

≤ 2020 | Q1/2021 | Q2/2021 | Q3/2021 | Q4/2021 | 2022 | 2023 | ≥ 2024

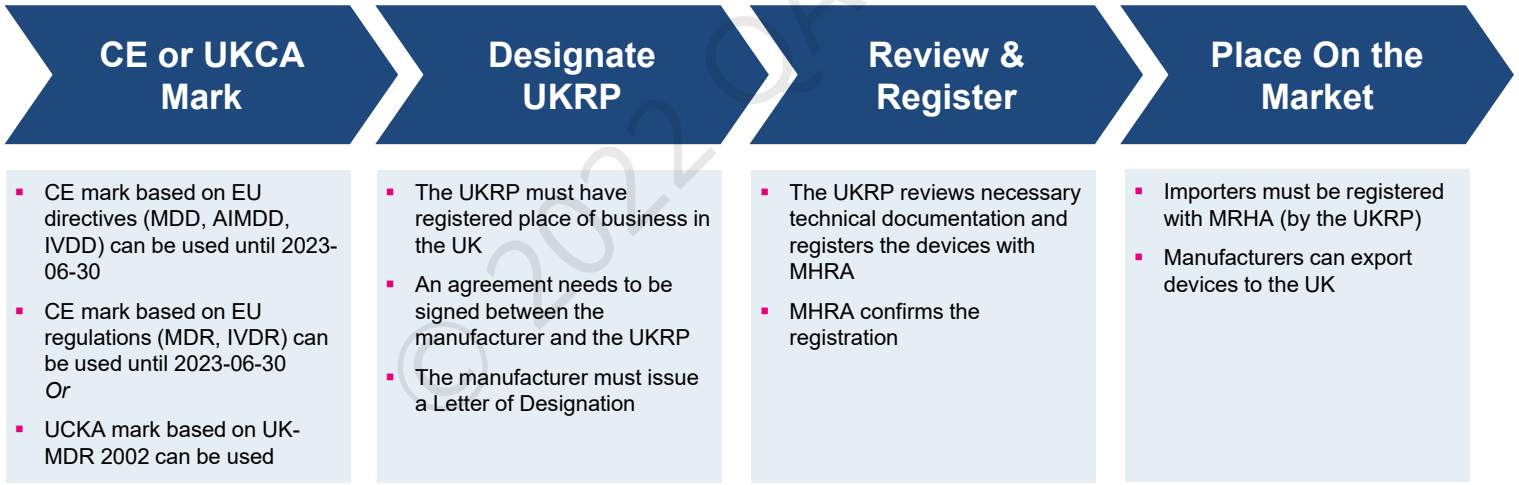
2021-04-30
The following devices must be registered with MHRA:
- Class III
- Class IIb impl.
- Active impl. MD
- IVD List A

2021-12-31
The following devices must be registered with MHRA:
- Class I
- Custom-made
- General IVDs

2023-06-30
Devices must be marked with UKCA marking

- CE mark (MDD, IVDD, MDR or IVDR) still accepted

From 2022-01-01 Devices Must Be Registered With MHRA Before Placed On the Market



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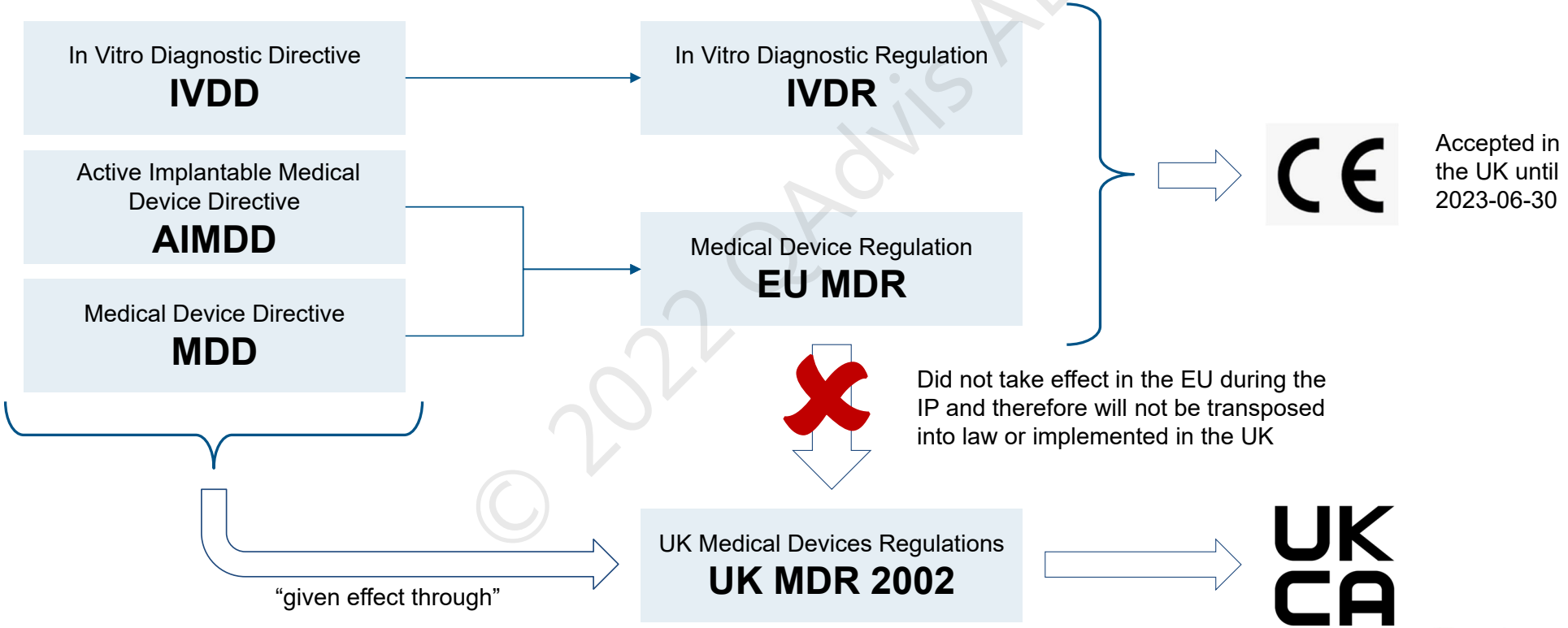
UKCA Marking

- Conformity Assessment with respect to the UK Medical Devices Regulations 2002 (UK MDR 2002)
- Available for manufacturers from 2021-01-01
- “UK Conformity Assessment Bodies” (UKAB) issues UKCA certificates (compare to Notified Bodies)
  - A bottle neck resource, similar to EU
  - If possible, use the same as your NB
- Very similar to CE marking against AIMDD, MDD or IVDD

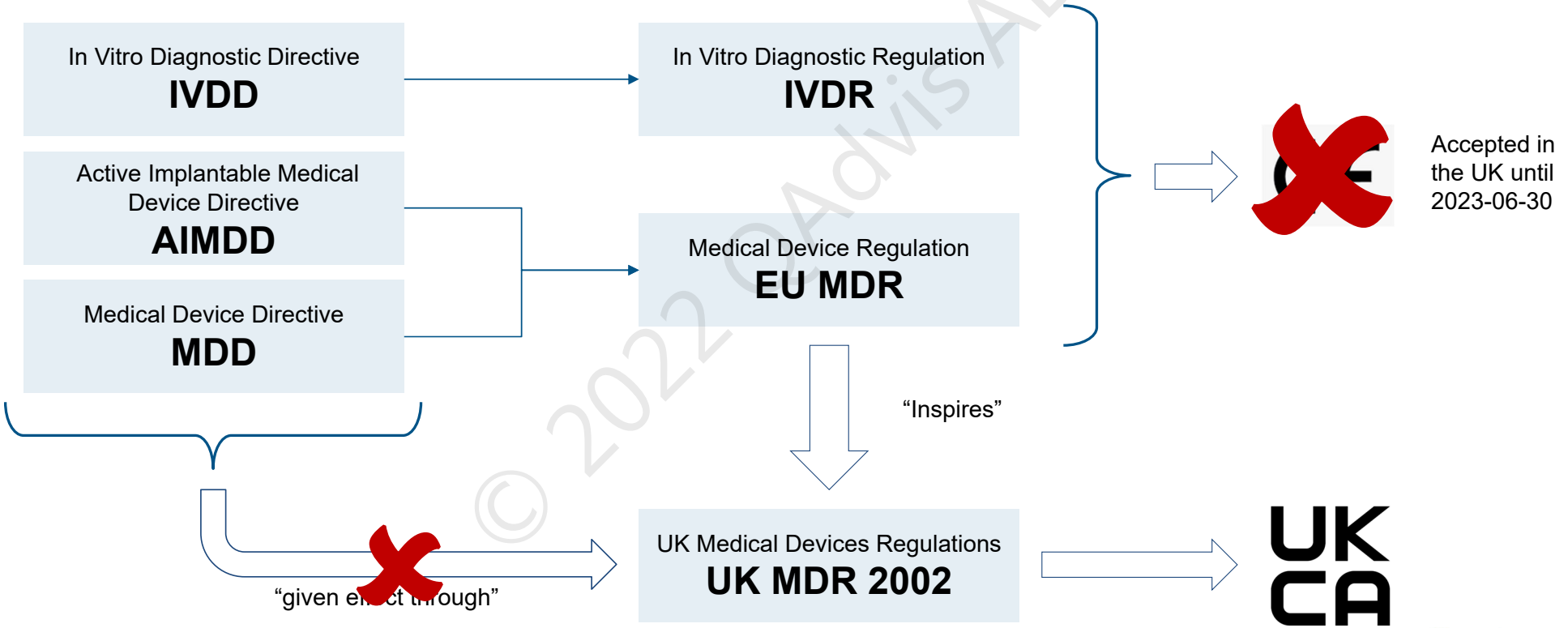
Relationship Between UK and EU Legislation – Up to 2023-06-30



UKCA Marking – What Happens After 2023-06-30?

- MHRA aims at updating the UK-MDR 2002 by 2023-07-01
- Already UKCA marked devices need to be reassessed
  - Compare MDD/IVDD to EU-MDR/IVDR transition
- “Grace periods” are expected to exist, both for CE marked and UKCA marked devices
  - Compare to EU-MDR (article 120(3)) and IVDR transitions (article 110(3))
- The updated UK-MDR 2002 is expected to be very similar to EU-MDR and IVDR

Relationship Between UK and EU Legislation – After 2023-06-30



A Careful “Marking Strategy” Must Be Elaborated

- Pay attention to when MDD/IVDD certificates or DoCs expire, may lead to different strategy if early or late expiration
  - Especially if using MDR article 120(3) or IVDR article 110(3) to stay on the market
- Decide if you are aiming at MDR/IVDR CE marking prior to 2023-06-30 or not
  - May lead to different strategies for UKCA marking depending on the date
- Decide if you are aiming at UKCA marking prior to 2023-06-30 or not
  - Affects the need for re-assessment
  - A window of opportunity for self-certifying devices, especially if you expect to be “up-classified”
- If you are in the need of a UKAB
  - Start the process as soon as possible

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MHRA Registration

- Must be done before placing devices on the market
- Must be done by a designated UKRP
- To facilitate registration, manufacturers are advised to
  - Know their GMDN codes and product structure
  - Have consistency between DoCs, certificates, technical documents, product labels, product lists, LoDs, IFUs, etc
  - Have all signatures in place as expected
- Requires MHRA confirmation before valid
- Registered devices publicly available in the PARD (Public Access Database for Medical Device Registration (mhra.gov.uk))

Some Advice to Manufacturers To Facilitate Registration

- MHRA registration is based on GMDN codes, these must be known
- Know your product structure
  - Device, in-house device, custom-made device, accessory, system or procedure pack
  - Ref. numbers, UDIs (optional) must match
  - Declarations and statements must match
- Product information (name, version, etc) must be consistent throughout documentation
  - E.g. DoCs, certificates, labels, product list, LoDs, IFUs
- Documents must be signed accordingly

A Couple of Other Things…

- Product Labelling
  - No changes needed as long as CE mark is basis for registration
  - UKCA mark must be added at the time of UKCA marking (dual labelling is accepted)
  - UKRP contact info must be added at time of UCKA marking
  - No specific symbol (yet) available for UKRP
  - Also, pay attention to the requirements for placing devices on the market in Switzerland after 2021-05-26 (for medical devices)
- For Covid-19 test manufacturers
  - Before MHRA registration devices must pass a review called “Corona Virus Test Device Approval” (CTDA)
  - For further info see: https://www.gov.uk/guidance/covid-19-test-approval-how-to-apply
  - Adds substantial cost to the registration procedure

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“UK Responsible Person” (UKRP)

- The role of the UKRP is to serve as the manufacturer’s liaison and contact point with the MHRA
- Must have a registered place of business in the UK
- Should be designated before first registration
  - Formal Agreement and Letter of Designation required
- Disclosed to the MHRA at the time of first registration

UKRP Role Definition According To MHRA 1(2)

- 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
- Register manufacturers' devices at MHRA
- In response to a request from the MHRA, provide all the information and documentation necessary to demonstrate the conformity of a device

UKRP Role Definition According To MHRA 2(2)

- Provide samples of a device to the MHRA or allow the MHRA access to the device
- 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 the applicable Regulations and inform the MHRA

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UKRP Services Offered by QAdvis

- Initial review of the technical documentation and declaration of conformi
  for the devices, to ensure compliance with the UK MDR 2002
- Issue review report

Initial

- Registration of manufacturer and devices in MHRA's Device Online Registration System (DORS
  including updates/changes/withdrawals
- Issue of UKRP certificate (if requested)

Fixed Fee

- Keep available, and safeguard, a copy of the technical documentation for the devices
- Act as liaison and contact point for MHRA
- Inform manufacturer about updates and changes to the regulatory landscape within the UK
- Grant the right to manufacturer to use QAdvis UK Ltd's name and address on the product labeling

Annual

- Optional services may be requested for additional regulatory guidance and support (will be quoted separately)

Optio-nal

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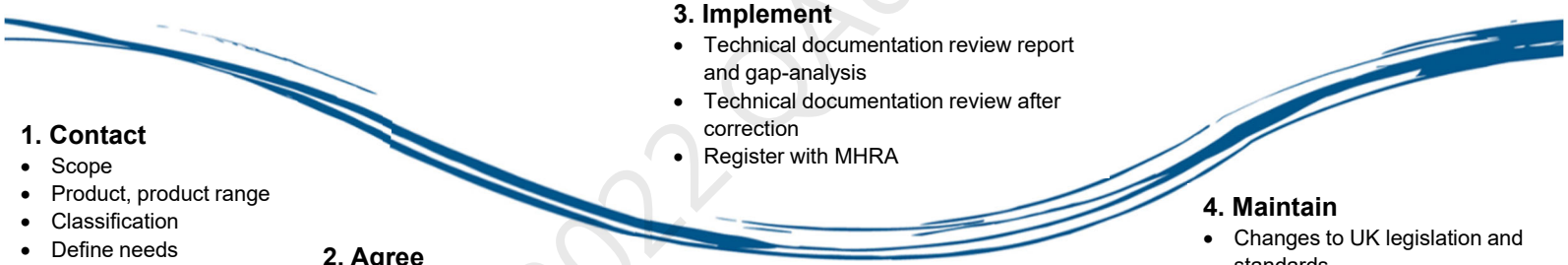
The Process From Contact to Maintenance



1. Contact
- Scope
- Product, product range
- Classification
- Define needs
- Quotation

2. Agree
- Define roles & responsibilities
- Access to, and review of, technical documentation
- Written agreement
- Mandate

3. Implement
- Technical documentation review report and gap-analysis
- Technical documentation review after correction
- Register with MHRA

4. Maintain
- Changes to UK legislation and standards
- Changes of scope and product range
- Renewals of MHRA registrations
- Support in MHRA communication

Why QAdvis?

- Easy access and communication to our Scandinavian team of regulatory professionals (important to find the right people to guide you)
- Good relationship with Swedish MPA and UK MHRA and active members of both the EAAR and the UKRPA organizations
- Independent professional legal representation focusing on regulatory aspects, not distribution/supply chain
- Avoids the need to share technical documentation with distributors/importers
- 10 years of experience from with European Authorized Representative services and by now 1,5 years of UKRP experience

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Advice for Manufacturers

- Designate a knowledgeable UKRP early on to guide you through the process
- Consider an independent professional UKRP focusing on regulatory aspects, not distribution/supply chain
- Understand the development of a new UK regulatory landscape and start developing a “Marking Strategy”, including UKCA, as soon as possible
- Avoid potential shortage of UK Conformity Assessment Body similar to EU NB shortage, if possible, use your NB also as a UKAB

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