Qserve®

.....the practical approach

UK Responsible Person

UK Market Access

Your Global MedTech Partner for **Regulatory Affairs, Quality Assurance** and **Clinical Trials**

Europe - The Netherlands (HQ) - Germany - United Kingdom - France - Belgium - Italy | USA | China

UK Responsible Person - UK Market Access

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Qserve Group

Qserve offers practical support to accelerate market approval. Our philosophy is to optimize and customize advice; our practical approach supports each individual company in the most efficient and cost-effective manner. Qserve, as a global leading consultancy, provides a complete and global solution by offering a complete package of regulatory, quality and clinical services.

Global presence,local service.

Why choose Qserve?

Strong international team with technical, regulatory, quality and clinical competence.

- Legal representation: UKRP, China Agent, US agent, EU Auhtorized Rep.
- Ex EU Notified Body staff
- 100% Medical Devices and IVD
- Practical approach
- Global presence, local service
- Native speakers in 12 languages
- Market access – Global registration

#1

UK market access after January 1st, 2021

Brexit introduced a new route to market in the UK including new product marking: the UK Conformity assessment mark (UKCA). Manufacturers outside the UK will have to designate a UK Responsible person (UKRP) to register their devices with the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Qserve will offer this service, where Qserve's office in Farnborough will be registered with MHRA as a UKRP with access to the MHRA database for registering manufacturers' medical devices and IVDs. As the UKRP, we are required to ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that the appropriate conformity assessment procedure has been carried out by the manufacturer. We are also required to keep available copies of the technical documentation, declaration of conformity, and any relevant certificates, including amendments and supplements, for inspection by the MHRA.

#2

What are the responsibilities of a UKRP, as offered by Qserve?

1) Check the CE certificate (if applicable), the DoC and technical documentation. Qserve will not re-review the technical documentation but will check for completeness to ensure it is appropriate and valid.
2) Register the medical devices / IVD in the MHRA database.
3) As UKRP, Qserve will act on behalf of your company with the MHRA:
    a) Responding to requests from the MHRA and provide the MHRA with information and documentation necessary to demonstrate the conformity of a device.
    b) Forward to the manufacturer any request by the MHRA for samples or access to a device, and ensure that the MHRA receives the samples or has been given access to the device.
    c) Cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if not possible, mitigate the risks posed by devices.
4) Qserve will communicate any complaints and reports received from healthcare professionals, patients and users about suspected incidents related to the registered devices/IVDs.
5) The UK legislation will continue to use the Medical Device Directive and the IVD Directive until new legislation is put in place.

#3

What is the advantage of engaging Qserve as a UKRP?

1) Located in Farnborough

Verified access to MHRA database

2) Independent

Since Qserve is an independent party, there is not a conflict of interest between Qserve and the manufacturer. Distributors often work with several manufacturers and this can create issues.

3) Respected group of experts

a) The UKRP is the first point of contact for regulatory issues with MHRA. Qserve has a knowledgeable team who will understand the communication they are receiving. Distributors who are not authorized representatives may not have staff with regulatory knowledge and may not understand the relevance of the communication.

b) As a Qserve client, you will be made aware of any/all changes to the UK legislation, ensuring that your business is minimally impacted.

c) Qserve's strengths:

- Diverse team that supports regulatory, clinical, and quality services
- Support with UKCA regulation
- Global footprint, local service

#4

What will a Qserve UKRP require from manufacturers?

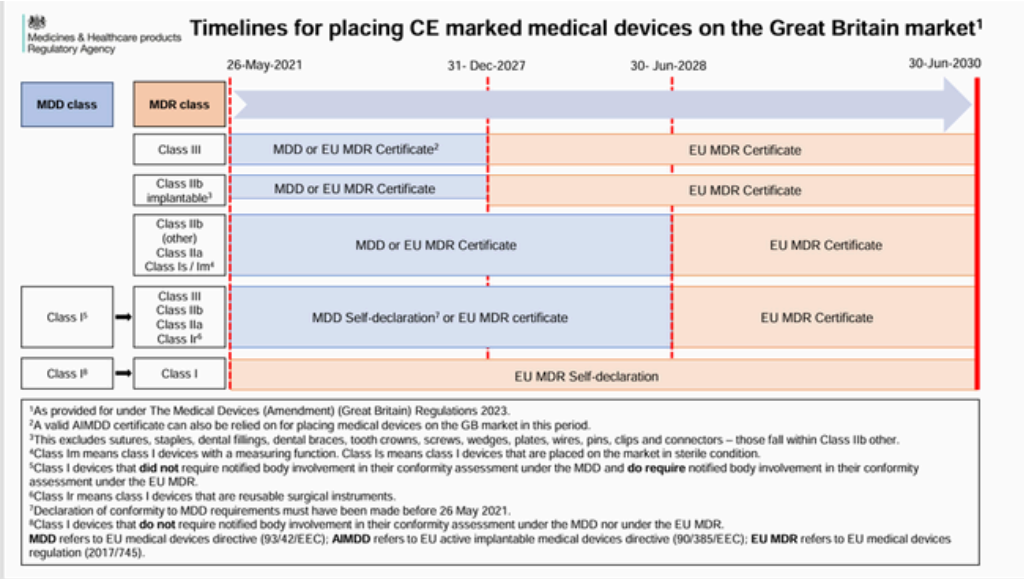
1) Access to the relevant technical documentation, the DoC and the CE certificates, either hard copy, electronically, or via secured access to the server of the manufacturer.

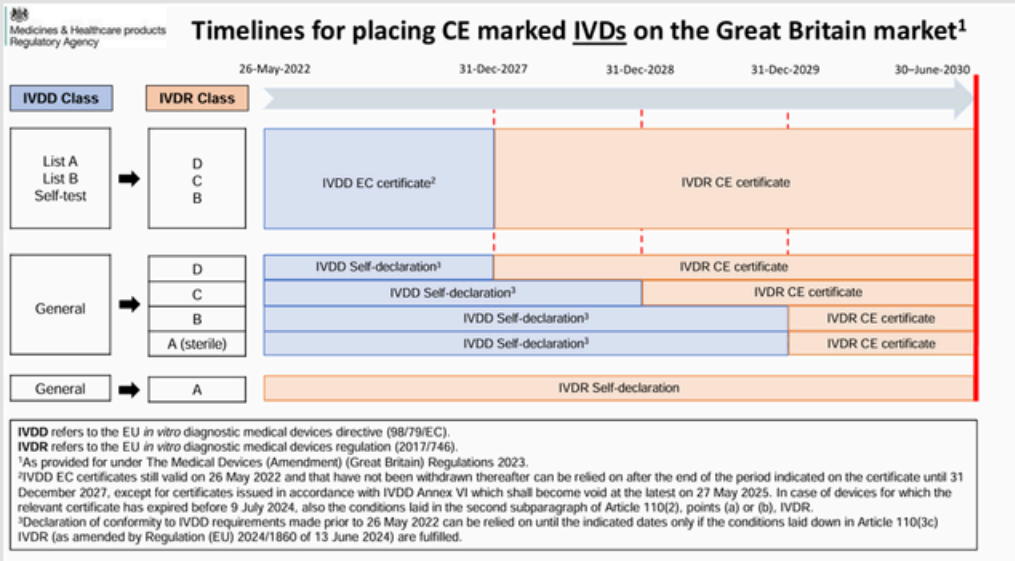
2) List of devices grouped by GMDN codes.

3) A valid/signed contract between the manufacturer and Qserve UKRP.

Note: as UKRP, if MHRA contacts Qserve, we must have access to the latest technical documentation, including the changes/fixes. This can be supported with change rationale.

#5 What are the timelines?





#6

What are the next steps to place medical devices and IVDs on the market?

- Review the UKRP contract
- Discuss the list of devices and group them by GMDN codes
- Sign a contract with Qserve
- Qserve UKRP will register devices/IVDs
- Prepare Regulatory strategy for UKCA mark
- Contact Notified Body for review of technical file for UKCA where applicable
- Prepare labeling conform UKCA

#7

What does the device registration process look like?

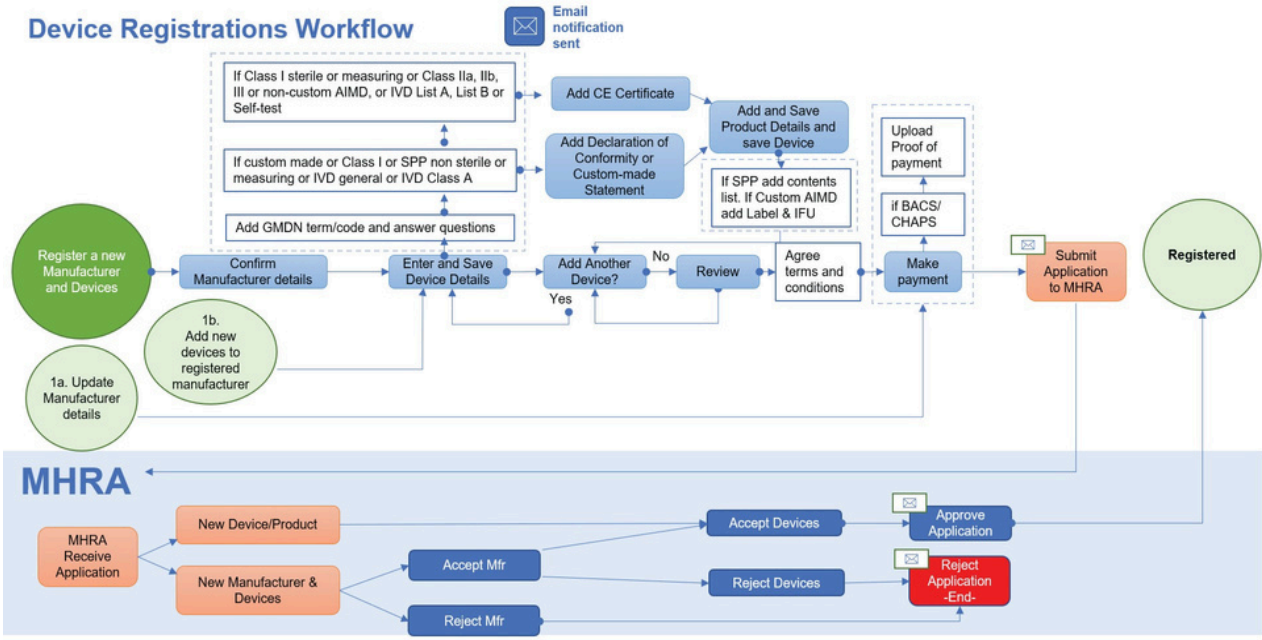


Figure 1. Device Registration Workflow as provided by the MHRA.

#8

What does the Qserve UKRP service cost?

Item	Description	Price in GBP
Qserve fees		
UKRP Service	· Use of Qserve name as UKRP · Use of Qserve name as UKRP on labeling · Point of contact for the Competent Authority	£ 1575 / invoiced annually
Device registration	· Check if Declaration of Conformity and Technical Documentation are drawn up and made available · Registration of device in MHRA database	£ 120.00 / submission
Changes to registration	· Administration regarding changes in organization or device details in the MHRA database	£ 120.00 / change submission
Authority fees*		
Device registration	· For initial device registrations and additional device registrations in DORS after 1 April 2026, where the device falls under a GMDN category for which no fee has previously been paid, the MHRA will invoice the £300.00 annual fee on a pro-rata basis, calculated from the date of registration. · Please note that the date of this contract does not correspond to the date of registration; therefore, an exact pro-rata amount cannot be confirmed at the time the quote is issued.	£ 300.00 / period (1 April to 31 March)
UK PMS Services		
PMS service	· Delegate vigilance reporting activities to Qserve under the UK PMS framework	£ 825.00 / year (includes 6 hours)
QMS update	· Qserve to update QMS documents, to comply with UK PMS framework	Ad-hoc consultancy fee
Other		
Additional regulatory changes	· Updates of regulations or guidances initiated by MHRA that affect the database registration	Ad-hoc consultancy fee
Qserve InSight	· Qserve InSight continuously monitors UK regulatory developments and delivers timely alerts, expert summaries, and actionable guidance in one centralized platform to support ongoing compliance.	£ 455.00 / year

** An administration fee of 7% will be applied to the actual costs as stated in our General Terms and Conditions. This fee is imposed because Qserve serves as an intermediary for the payment of the authority fee, which is an integral part of the submission process.*

#9

Frequently Asked Questions (FAQ)

Q: Can Qserve provide a verification document or certificate confirming the designation that Qserve's office in London is officially listed with MHRA as UKRP?
A: *The MHRA does not distribute such certificates or documents. We can provide confirmation showing that Qserve is MHRA registered.*

Q: MHRA costs per GMDN code registration; is it a once-off payment to the MHRA? Or recurring?
A: *For initial device registrations and additional device registrations in DORS after 1 April 2026, where the device falls under a GMDN category for which no fee has previously been paid, the MHRA will invoice the £300.00 annual fee on a pro-rata basis, calculated from the date of registration.*

Q: Is the GMND code compulsory and provided with the registration in the MHRA?
A: *Yes, this is a requirement in the database. Without the GMDN code, the device cannot be registered.*

Q: When must the listings be updated in the MHRA? (for example, in case of new releases or software patches). Does the MHRA require registration for each major release or only new releases, including patch updates?
A: *Qserve must register the product once, and unless there are no significant changes, we are not required to notify the MHRA. In most cases, a simple patch or bug fix that does not affect the intended use or other significant aspects, is not considered a significant change. Minor software updates that do not affect a medical device's performance, safety, risk classification, or intended purpose do not need to be registered separately in the MHRA database as new devices. This can be discussed with Qserve before registration updates.*

Q: Who is responsible for reporting incidents to the MHRA?
A: *Under the UK MDR 2002 (as amended) and updated UK PMS requirements (June 2025), the manufacturer remains legally responsible for reporting incidents to the MHRA. While both the manufacturer and UK Responsible Person (UKRP) have roles in vigilance, reporting activities may be delegated to the UKRP, provided this is clearly defined in a written agreement. However, such delegation does not transfer legal responsibility, the manufacturer remains fully accountable for compliance with incident reporting obligations.*

Q: Who keeps track of all the regulatory updates in the UK?
A: *Qserve InSight helps companies stay compliant by monitoring UK regulatory changes and translating them into clear, actionable insights, including timely alerts, expert summaries, and impact assessments — all in one centralized platform.*

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Regulatory Af fai rs

Clinical Af fai rs

Training Academy

Quality Compliance

IVD

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