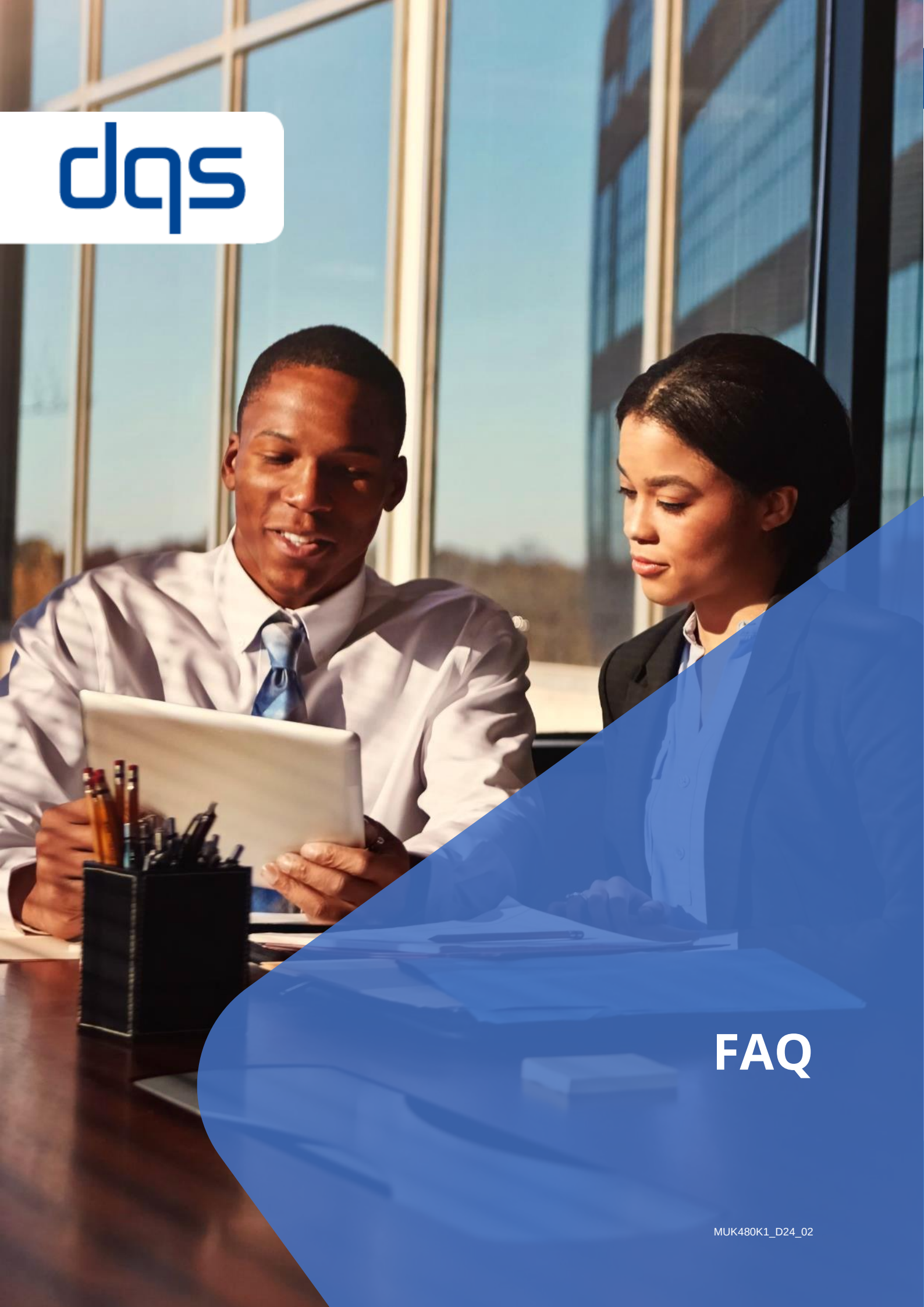

FAQ

MUK480K1_D24_02

Introduction

This document represents a collection of questions we have received and our responses. Unfortunately, we are not able to respond to specific questions regarding your device or strategies for regulatory or clinical pathways outside of our Structured Dialogue and routine support programmes for conformity assessment.

Please be aware that although every care has been taken to ensure that the information contained in this document is accurate at the time of publication, the UK regulatory framework is evolving rapidly and therefore there is no guarantee that the information remains correct at the time of reading. Please refer to the underlying legislation for the current situation in the UK. DQS MED UK accepts no liability for any loss or damage caused, arising directly or indirectly in connection with reliance on its contents except to the extent that such liability may not be excluded in law.

The answers to the questions are based on the DQS way of working and if you are applying to another UK Approved Body we advise that you consult directly with them.

For DQS potential and actual customers, please contact dqs-uk@dqs.de for more information about Structured Dialogue and Project Management programmes. You can also use the same email address to raise questions that we have not covered herein. We will incorporate your questions into our next release of this document.

In this document, we use the term “routes to market” to describe the regulatory pathways that manufacturers can use to legally place product on the market of a specific jurisdiction.

Abbreviations:
AB – Approved Body
CAB – Conformity Assessment Body
CE – Conformité Européenne (European Conformity)
DoC – Declaration of Conformity
DQS MED UK /DQS – DQS Medizinprodukte UK Ltd
EEA – European Economic Area
EU – European Union
EU MDR – European Union Medical Device Regulation 2017/745
GB – Great Britain
MDD – Medical Devices Directive 93/42/EC
MHRA – Medicines & Healthcare products Regulatory Agency
NB – Notified Body
NI – Northern Ireland
UK – United Kingdom
UK MDR - Medical Devices Regulations 2002 (SI 618), as amended by the EU Exit Regulations of 2019 (SI 791), 2020 (SI 1478) and 2023 (SI 627)
UKCA – UK Conformity Assessed
UKRP – United Kingdom Responsible Person

UKCA MARKING FOR MEDICAL DEVICES

What is UKCA marking for medical devices?

The UKCA is a marking that is used to demonstrate that products meet the conformity assessment requirements set out in UK legislation and can be placed on the market of Great Britain (England, Scotland and Wales). It is similar to CE marking for the EU.

What jurisdictions recognise UKCA marking for medical devices?

The only jurisdiction that recognises UKCA marking is Great Britain. CE marking is still required in Northern Ireland.

What are the other routes to market in Great Britain?

UKCA is the national route to market. Currently, Great Britain also recognises CE marking.
In addition, the UK Government is discussing International Recognition (formerly known as domestic assurance), where approvals made by trusted jurisdictions can be leveraged as meeting common requirements in the UK legislation.

What types of medical devices can use UKCA marking as a route to market?

UKCA marking applies to all medical devices, including in vitro diagnostic devices, that meet the definition of a medical device.
Note: the UK MDR has exclusions.

Where can I find the UKCA requirements?

The approach is similar to that of the EU Directives, as the UK legislation is based on these Directives, but it is important to remember that the UK MDR has received a number of updates, including those documented in the main body of the legislation (or parts) and Schedule 2A, which describes modifications to the Annexes of the EU Directives.
In addition, MHRA has published guidance for specific scenarios, such as virtual manufacturing.

Is the UK MDR based solely on the EU Directives?

The underlying content of the UK MDR is currently based on the EU Directives, as they applied at the time of Brexit. However, there have been amendments, for example, around virtual manufacturing. It is important to refer to the latest version of the UK MDR, including Schedule 2A, as well as the transitional arrangement and other amendments.

How long will CE marking be accepted in Great Britain?

The current guidance states that CE marking will be accepted up to 30 Jun 2030, at the latest depending on the type of device. This information is also available as an infographic.

Can I use CE marking as a route to the GB market for new products?

The current exemption allows new devices with CE marking to be placed on the market of GB. From 1 July 2025, new devices cannot be placed on the GB market without UKCA marking, unless requirements under SI 2023 No. 627 are met.

Will I be able to place devices on the market of GB where the CE certification under MDD has expired, but the marking is valid under regulation (EU) 2023/607?

The MHRA has stated that the route to market depends on "a valid declaration and CE marking", not specifically the certification. More information can be found in guidance and in the relevant legislation.

If my product has CE marking, can I add UKCA marking without any further activities as they are both recognised by the UK Government?

No, although both CE marking and UKCA marking are recognised by the UK government, the requirements are different. The markings have different meanings and conformity to one set of requirements does not automatically demonstrate conformity with the other. In order to place either CE or UKCA marks on products, the specific requirements must be met, including obtaining a 3rd party conformity assessment certificate, if required, and a DoC made to the specific set of requirements.

Can I apply UKCA marking where I have completed a CE conformity assessment?

No, even though CE marking is currently accepted as a route to market, UKCA marking can only be applied where there is a UKCA conformity assessment and DoC.

If my product has CE marking, is there anything else I need to do to place product on the market of GB?

Yes, additional actions are necessary as CE marking only meets part of the requirements to place product on the market in GB. There are further requirements, for example, registering the product with MHRA, appointing a UKRP, and ensuring that the QMS meets the requirements, including reporting to MHRA and PMS.

If my product has CE marking, is there anything else I need to do to place product on the market of NI?

Yes, additional actions are necessary as CE marking only part of the requirements to place product on the market in the UK, including NI. There are further requirements, for example, registering the product with MHRA, appointing an authorised representative, and ensuring that the QMS meets the requirements, including reporting to MHRA and PMS.

Can I use the same declaration of conformity for UKCA and CE?

The declaration of conformity needs to reflect the legislation against which conformity is being declared.
As the UKCA and CE requirements are different, it is recommended that separate DoCs are made following the guidelines for each legislation.

How long is UKCA Certification valid for?

The UK MDR allows for issuance of certification valid for up to 5 years, provided all requirements are met. In some circumstances, shorter certification may be issued, and your UK AB will provide the full details.

If I use the abridged route to certification, will my product have a 5-year UKCA certificate?

The duration of the certification will be determined based on the activities performed by the UK AB. In general, the certificate duration is aligned to the CE certification cycle on which the abridged assessment was based.

Can I align UKCA and CE Certification cycles?

We are seeing most UK ABs with sister EU NBs offer an aligned service to prevent duplication of assessment activities, and DQS will adopt this approach. However, where you are using unrelated UK ABs and EU NBs, under the current legislation, the certification activities will run in parallel and therefore there is no advantage to alignment.

What is the abridged route to UKCA certification?

The abridged route to UKCA certification allows your current CE certification to be leveraged as meeting some UKCA requirements, subject to verification activities by the UK AB. In addition, the UK national differences are assessed as a new application.
In future, we may see the opportunity for other regulatory approvals from trusted jurisdictions to be suitable for the abridged route to UKCA certification, but at the moment it is limited to CE certification.

If my product has CE Certification, when is the best time to apply for UKCA Certification?

We recommend that you consider your current certification, its duration, your product risk class, and your EU MDR transition plans, amongst other factors when determining the best timing.
We have prepared client information notes and other materials to guide you in your planning.
If current DQS customers have any further questions, please speak with your dedicated DQS Regulatory Affairs Manager who will be able to support you.
New customers may request Structured Dialogue sessions from dqs-uk@dqs.de

If I transition to UKCA leveraging CE under the EU Directives, am I able to implement significant changes to my product without invalidating the certificate?

Once a UKCA certificate is granted it is managed under the UK legislation independently of the EU Directives. Whilst there is no process for updating the CE certificate based on the EU Directives, changes can be made to the UKCA certificate.
Please note: any significant change may invalidate your certificates and need to be implemented following the certification body's change process.

Can I apply for abridged UKCA certification if my product has CE certification under the EU MDR?

At DQS, the abridged route UKCA certification is open to all CE certification, independent of the underlying legislation. The underlying legislation will affect the amount of work that is to be done by the UK AB. However, our experience shows that although the UK legislation is aligned to the EU Directives, the updates and evaluations manufacturers implement for the EU MDR means that the technical documentation is generally in a better position for facilitating the abridged route to UKCA. We, therefore, recommend abridged UKCA after transitioning to the EU MDR.
For some products, the abridged route is not applicable. For full details, see our client information note on the abridged route to UKCA.

How are UKCA certificates renewed?

UKCA certification renewal will follow the requirements of the UK MDR at the time of renewal and consider the past 5-year cycle. All activities required for the certification cycle must be completed before the renewal.

Who is legally responsible for medical devices placed on the UK market?

The UK market has adopted the same structure as the EU. The manufacturer named on the label is the legally responsible manufacturer.

Can I transfer existing certification to DQS?

Yes, we have a transfer process for UKCA certification and ISO 13485 certification.
You cannot transfer existing CE certification; however, you can leverage this certification as evidence of meeting some of the UKCA requirements.
Where there is existing certification, we need to assess whether the activities were performed correctly and completely. The more information available, the more comprehensive our assessment and the fewer gaps we are likely to find. All gaps will need to be addressed by additional assessment activities before certification.

LEGISLATION STRUCTURE

What are the differences between UKCA and CE marking?

At the point of Brexit, UKCA marking requirements were largely aligned to EU requirements. However, the EU requirements for CE marking have evolved, not least because of the implementation of the EU MDR and EU IVDR. In parallel, the UK requirements have changed.

Will the UK align to the EU requirements?

At the point of Brexit, the UK intention was to align to the EU MDR. Indeed, had the implementation of the EU MDR not been delayed due to the COVID response, the UK would have exited with this legislation.

What is expected is that, although the long-term goal is alignment, until the full impact of the EU MDR and IVDR on device availability and innovation has been assessed, it is unlikely that the UK and EU requirements will be fully aligned.

How will the new legislation in the UK affect products with UKCA marking before the date of implementation?

As with all regulatory change, certification requirements will change, and the new requirements will need to be met. There is likely to be a transition period. Once the new legislation is published, we will be able to consider how the transition period impacts certification.

Where my device needs to comply to UK MDR and another legislation (e.g. machinery / PPE), how do I manage the transition?

The transitional arrangements set out in the Medical Devices Regulations 2002 for medical devices will remain unchanged.

The UK Medical Device Regulations provide that, where a device comes within the scope of the Regulations and other product safety or health and safety legislation, a person must not affix a UK marking to the device unless the relevant requirements of the other legislation are also satisfied.

The UK Government intends to introduce legislation that extends the recognition of CE marking to non-medical device legislation indefinitely. Also see (announcement - https://www.gov.uk/guidance/using-the-ukca-marking and Draft legislation - https://www.legislation.gov.uk/ukdsi/2024/9780348260311) for 21 regulations will mean that the relevant requirements will be satisfied if EU requirements are met (including compliance with the relevant essential requirements and conformity assessment processes for the other Regulations).

This means that whilst there is continued recognition of the CE mark for legislation captured within UK's recently laid legislation it will be possible, for example, to UKCA mark a medical device even if the aspects governed by machinery legislation comply with EU rather than UK requirements.

Please see guidance for further information: Policy Update: Placing products on the market in Great Britain using UK or EU product markings (publishing.service.gov.uk)

STANDARDS

Where do I find the designated Standards?

The list of designated Standards for the UK is available here.

What do I do if I have tested to a standard or a version of a standards that is not listed as designated Standard?

Testing to the designated standards allows manufacturers claim "presumption of conformity"; but does not replace the essential requirements. If you place a product in more than one jurisdiction, you may need to demonstrate compliance with multiple requirements for the same technical aspects and therefore conformity may be demonstrated by testing to more stringent requirements than those required for a given jurisdiction. It is up to you to justify how your testing programme meets the UK requirements. More information about designated standards can be found here.

LABELLING

How do I label my products for the GB market?

The latest information at the time of writing is here.
Note: the labelling requirements have evolved since Brexit. This also applies to physical marking on the device, as well as labelling and IFU.

Can both UKCA and CE marking appear on the same device & labelling?

Dual marking is permissible in the UK where both UKCA and CE conformity assessment are completed and, to our knowledge, there is no precedent of disallowing dual marking in the EU. In both cases, the applicable marking requirements must be met, including clarity of the information and its applicability in each jurisdiction.
Where you have a NB other than #0297, it is recommended that you confirm their position on dual marking.

When do I need to update my labelling to continue placing product on the market of GB?

The requirement to update labelling depends on the chosen route to market, taking into consideration the transition requirements outlined in SI 2023 No. 627.

Do the UKRP contact details need to be on the labelling where CE is used as a route to market?

The current requirements to update labelling state that the UKRP details, where applicable, are only required where UKCA marking is affixed.

Does the UK have a requirement for a UDI on the label?

The current UK legislation does not require compulsory UDI, although there are discussions to adopt this approach. The local database does have facilities for registering UDIs and it is understood that using the same UDI for different markets to avoid the same clinical device having multiple UDIs is preferred by MHRA.
Note: There is a drive from IMDRF to standardise how manufacturers assign UDIs to their device for different markets to facilitate global tracking/tracing however that work is in the early stages.

Can a UKRP act as an EU Authorised Representative and vice versa?

No, a UKRP needs to be located in the UK and an EU Authorised Representative needs to be located in the EU. As the UK is no longer in the EU, a UKRP cannot be an EU Authorised Representative. However, many organisations have sister sites in each jurisdiction.

Where does UKRP information need to be on the labelling?

The UKRP information should be on either the product labels or IFU, or both.
Note: Currently, the UKRP information only applies to labelling where UKCA marking is used.

Can I have more than one UKRP as I have more than one distributor?

The MHRA guidance states that a manufacturer should appoint only one UKRP for all their devices.

Is there an agreed symbol to represent the UKRP?

To date, there is no agreed symbol published for the UKRP.

How do I find a UKRP to represent my business in the UK?

There are many organisations that offer this service. As their details appear on the labelling, it is important to ensure that the selected UKRP meets your long-term requirements.
There is an association for UKRPs: UK Responsible Persons Association (UKRPA) enquiries@ukrp-association.org.

Where a manufacturer has used CE as a route to market, how do I find the contact information for the UKRP?

Currently, there is no requirement to provide the contact information of the UKRP on the label where CE marking is used as a route to the GB market. The information should be accessible through the MHRA Public Access Database.

VIGILANCE

What qualifications should UKRPs have? How do I select one?

The UK MDR, and particularly schedule 7A for GB and 19B for NI, sets out the role and responsibilities of a UKRP, but does not provide any information on the qualifications needed for a UKRP for medical devices or how to select one. It would be expected that the manufacturer performs their own due diligence considering the activities that they expect the UKRP to perform.
Also see MHRA guidance and there is an association for UKRPs: UK Responsible Persons Association (UKRPA) enquiries@ukrp-association.org.

Does the UKRP have any responsibility for the content of the TD?

The MHRA guidance states that the UKRP "must ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer".

Can a UKRP refuse my request to appoint them?

As the UKRP has specific responsibilities, for example, around ensuring that the declaration of conformity and technical documentation have been drawn up, they can refuse the request from the manufacture where they believe these requirements have not been met.

Can a UKRP state that they will only accept to be appointed if I contract them for specific consultancy activities?

As the UKRP has specific responsibilities, they can refuse a request to be appointed where they believe that requirements have not been met. It is at the discretion of the manufacturer how they address the deficiencies and whether they seek a second opinion.

Does the UKRP need copies of technical documents or just access to them?

The MHRA guidance states that the UKRP "must keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA". This means that they should have up to date copies of these documents.

As a virtual manufacturer based in the UK, do I need a UKRP?

The MHRA guidance states that only manufacturers based outside of the UK require a UKRP. As the legal responsibility lies with the manufacturer placing the product on the GB market, where a virtual manufacturer is situated in the UK, there is no requirement for a UKRP.
Additional guidance for virtual manufacturing is available.

Who is required to report vigilance events – the manufacturer or the UKRP?

The MHRA guidance states that the manufacturer, UKRP or NI Authorised Representative, shall notify MHRA about incidents and field safety corrective actions that meet the reporting criteria, including Periodic Summary Reports and Trend Reports.

When a device is placed on the GB market with CE marking, are there any vigilance reporting requirements in the UK?

The MHRA guidance describes the vigilance reporting requirements.

STAKEHOLDER

Do I need a UK importer or distributor?

The MHRA Guidance defines the roles and requirements for the importer and the distributor. You will need to determine what stakeholders need to be engaged for your business.
The UKRP may also be the importer or distributor. Where the GB importer is not the UKRP, there needs to be communication between the two parties as the UKRP must provide MHRA with a list of device importers.

Does the UK importer need to be on the labelling?

The importer has obligations around storage, transportation and label checking for the CE or UKCA mark. However, the importer's name and address will not need to be present on the label unless they are acting as the UKRP.

Do distributors and importers need a UKRP?

The MHRA guidance states that importers and distributors are not required to appoint a UK Responsible Person

The manufacturer or the UKRP is required to provide the MHRA with details of device importers. Further guidance on device registrations.

Do distributors and importers need to notify the manufacturer of their activities?

The MHRA guidance states that the importer is required to inform the relevant manufacturer or UK Responsible Person of their intention to import a device.

Can a single manufacturer have more than one UKRP?

The MHRA guidance states that a manufacturer needs to appoint a single UK Responsible Person for all of their devices.

Registration with MHRA. How do we register devices with the MHRA?

Information on registering medical devices is available on the UK government website.
It is important to note that this information needs to be kept up to date.

At what stage do we register medical devices with MHRA?

All medical devices, including IVDs, custom made devices and systems or procedure packs must be registered with MHRA before they can be placed on the GB market.

Do I need a contract with a UK AB before registering devices?

No, the registration process is independent of the UKCA conformity assessment, as devices may be placed on the market through other routes, e.g. CE marking under the transitional arrangement per SI 2023 No. 627.
For devices that have not been placed on the GB market and UKCA is the chosen route to market, contact dqs-uk@dqs.de for information about when it is best to register your devices.

How do I register medical devices that have an expired CE certificate that is valid under regulation (EU) 2023/607?

Full details of registration requirements are provided by the UK government and there is a specific section on the registration of certain medical devices that have expired/expiring CE certification.

If I register my devices with CE certification, will I need to update the registration when I use UKCA as a route to market?

Yes, the MHRA guidance includes uploading and linking new conformity assessment and self-certification declaration documents to registered devices.

Once my devices are registered with MHRA, do I need to re-affirm the registration when there has been no change?

Yes, it is important to review your registration frequently to make sure it is up to date and this requirement should be reflected in your QMS processes. The Device Online Registration System, DORS, also has a review registration process that sends reminders to review your registration and confirm that it is up to date.

What information do I need to register my devices?

The MHRA Guidance lists the required information for registration.

How are records listed on the public register?

Records are listed on the Public Access Registration Database (PARD) for medical device registration.
Records are listed by:

- Manufacturer name.
- Address.
- MHRA Reference (account) number.
- Medical Device Type (Global Medical Device Nomenclature (GMDN®) Term).
- 5-digit GMDN® Code.

UK APPROVED BODIES (UK ABs)

What is the difference between EU NBs, NI NBs and UK ABs?

EU Notified Bodies (EU NBs) are designated by EU member states to perform 3rd party conformity assessment according to a specific EU legislation and can issue CE certification to demonstrate requirements are met.
CE certification allows manufacturers to place CE marking on their products and serves as a route to market in the EEA. A list of EU NBs can be found on the NANDO website.

NI Notified Bodies (NI NBs) are designated by MHRA to perform 3rd party conformity assessment according to EU MDR or EU IVDR and can issue CE UKNI certification to demonstrate requirements are met.
CE UKNI certification allows manufacturers to place CE UKNI marking on their products and serves as a route to market in Northern Ireland only. A list of NI NBs can be found on the UK government website. Importantly, not all UK Approved Bodies (see below) are NI NBs.

It is worth noting that despite the jurisdiction limitations relating to the marking, the current unfettered access provisions mean that the UK Government currently guarantees access for NI's businesses to the rest of the UK international market, such that CE and CE UKNI marked devices that can be placed on the NI market can also be placed on the GB market.

UK Approved Bodies (UK ABs) are designated by MHRA to perform 3rd party conformity assessment according to UK MDR and can issue UKCA certification to demonstrate requirements are met.
UKCA certification allows manufacturers to place UKCA marking on their products and serves as a route to market in Great Britain only. A list of UK ABs can be found on the MHRA website.

The post Brexit EU–UK Trade deal did not include a Body Mutual Recognition Agreement (MRA) for conformity assessment, therefore EU NBs are not recognised as UK ABs and cannot issue UKCA certification and UK ABs are not recognised as EU NBs and cannot issue CE certification.

The NI situation is slightly different as NI exited the EU, but not the common market. This means products still need to have CE marking. The NI NBs are not recognised as UK ABs or EU NBs and cannot issue UKCA or CE certification; however, most NI NBs have sister EU NBs and UK ABs.

What do UK ABs do?

The MHRA guidelines describe the roles of UK Conformity Assessment Bodies (CAB), otherwise known as Approved Bodies (ABs). More detailed information is available in the UK MDR.

When do I need a UK AB?

UK Approved Bodies are required for 3rd party conformity assessments under the UK MDR. The MHRA guidelines state which products can be self-declared and which required 3rd party conformity assessment.
You only need a UK AB where UKCA marking is used as the route to market.

How do I select a UK Approved Body?

The MHRA website has a list of UK ABs. Not all UK ABs are designated for all type of devices and all conformity assessment routes, therefore, it is recommended that you check the scope meets your device portfolio before approaching the UK AB. Full information can be found on the MHRA website.

Once you have found a UK AB that covers your device type, you will need to engage with them to determine their availability and costs.

How do organisations become UK ABs?

All UK-based EU NBs became UK ABs on the 1st Jan 2021 for their scope of accreditation at that time. This roll over allowed UKCA certification activities to begin immediately.

Other organisations had to apply for designation and the process is defined in the UK MDR.

Does the UKCA mark differ where there is 3rd party conformity assessment?

Yes. Self-declared products use the standard UKCA marking. Where there is 3rd party conformity assessment, a 4-digit UK AB number is added under the UKCA marking.

DQS in the UK.
Is DQS intending to become a UK Approved Body?

Yes, DQS MED UK has started the application process. We expect to be designated in Q2 2025 but recognise that the UK situation is evolving rapidly and, therefore, this timeline is subject to change. We will provide regular updates on our progress.

Does DQS have a UK Approved Body number?

No, the UK AB number is assigned by the UK Government when the legal entity obtains its first designation. To date, DQS MED UK does not have a designation in the UK.

Will DQS only offer UKCA certification?

No, DQS will have an accreditation to ISO 17021-1 for delivering accredited ISO 13485 assessments and certification globally. In addition, our customers can use any global DQS office for one-stop access our DQS product portfolio (see our website for more details).

Medicinal. Does MHRA accept drug consultations from other competent authorities?

Acceptance of existing consultations is on a case-by-case basis. Consultations with the MHRA will be initiated once you apply for UKCA certification.

Can devices with medicinal compounds be considered for the abridged route to UKCA?

The abridged route is considered on a case-by-case basis; however, because of the consultation process, devices with medicinal components are rarely suitable for the abridged route unless the original certification is provided by our sister NB v0297.

Can devices with components derived from animal tissue be considered for the abridged route to UKCA?

The abridged route is considered on a case-by-case basis; however, because of the differences in the veterinary requirements between the UK and EU, devices with substances derived from animal tissue are rarely suitable for the abridged route unless the original certification is provided by our sister NB 0297.

Is the UK classification of medicinal compounds the same as that for the EU?

In most cases, the UK and EU are aligned; however, there are some differences and, therefore, manufacturers of devices with medicinal compounds should consult the British Pharmacopoeia for information.

MANAGING COMBINED UKCA AND CE MARKING

If I have tested to harmonised standards and have CE certification, do I need to retest and rewrite my technical documentation referencing the designated standards?

An addendum approach is acceptable, where the manufacturer aligns the standards used in the technical documentation with the designated standards and provides a justification as to how the applied standards meet or exceed the stringency of testing required in the designated standards.

Should I have 2 sets of technical documentation: one for EU MDR and UK MDR requirements?

It is up to the manufacturer how they address both EU and UK requirements. DQS accepts CE technical documentation with an addendum showing how the UKCA requirements are met. However, the documentation, including supporting data, must be in English.

Some of the designated standards are not the latest versions – can we use the latest version?

Best practice and state of the art are usually reflected in the latest version of the standards. Where the designated standards are not the latest standard, it is recommended that a justification be provided as to how the applied standards meet or exceed the requirements in the designated standards.

Where my product has CE and UKCA marks, do I report changes and vigilance to both the UK AB and NB? The same applies to the different competent authorities.

DQS has streamlined its processes for reporting to the certification body where the CE and UKCA conformity assessment is provided by DQS. You will only be required to make a single report to DQS for both the EU NB and UK AB.
If the CE or UKCA conformity assessment is provided by another organisation, you will

need to report separately to both organisations.

You will also need to report separately to MHRA and the competent authority responsible for your CE certification.
The reporting requirements should be reflected in your management system.

How do I apply for combined UKCA and CE applications?

Our Basic Data Form allows you to submit a combined application. DQS MED UK AB will work with our sister EU NB #0297 to perform combined assessments.

For a combined application, do we classify the medical device according to the UK MDR or EU MDR?

Where the UK MDR and EU MDR classifications are different you will need to perform 2 parallel classifications, one to each legislation for which compliance is being claimed.
Note: where the classifications are different, the abridged route to certification may not be applicable.

For the abridged approach, do I only need to provide the CE certificate?

Where CE conformity assessment is leveraged as meeting the UKCA requirements, we need to assess whether the CE conformity assessment was performed correctly and completely. The more information available, the more comprehensive our assessment and the fewer gaps we are likely to find. All gaps will need to be addressed by additional conformity assessment activities before certification.

Will CERs written for the EU MDR be acceptable for UK MDR?

Where the EU MDR CER meets the requirements of the UK MDR, then the document would be acceptable.

For devices new to the market (no former approvals) is a UK manufacturer required to have UKCA certification, or can they apply for CE certification and place product on the GB market using CE certification?

Whilst MHRA continues to recognise CE marking and UKCA marking, either route is possible.

Does the UK have an equivalent to EU MDR Article 117?

There is no equivalent article under the UK MDR. The response to the 2021 consultation suggest there will be such legislation in the future.

Will MHRA accept a grandfathering approach?

There is no specific legislation to underpin grandfathering; however, abridged assessments allow CE certification to be leveraged as evidence of meeting common criteria between the EU MDR and UK MDR.

Can the scope of the UKCA certification be different to the CE certification?

Yes, the proposed scope of the UKCA Certificate can be different as they are independent certifications. However, if the manufacturer is using the abridged approach, consideration needs to be given to the impact of the different scopes on the required assessment activities. Additionally,

where the CE and UKCA certification are provided by DQS, different scopes will add complications to providing ongoing combined certification delivery. Tailored information will be made available during the application process.

Can surveillance of CE and UKCA be combined?

We aim to combine activities wherever possible. A small increase in audit and TD review durations is needed to assess the national differences. However, combined service delivery is only possible where DQS provides both UKCA and CE certification services.

Does DQS MED UK consider Conformity Assessments by NBs other than DQS MED (NB#0297)?

Yes, manufacturers may apply for an abridged Conformity Assessment process with CE certification from any EU NB.
Once the conformity assessment is complete, any certification will be managed by DQS independently of the activities performed by the other EU NB.

If I use the abridged route to UKCA conformity assessment and my CE certificate expires and is not renewed, what will happen to the UKCA certificate?

Where your CE certificate is issued by a notified body other than DQS, UKCA will be managed as a stand-alone certificate and therefore changes to your CE certificate will be assessed separately to your CE certificate. For DQS CE conformity assessment customers, we offer a combined approach. If you choose not to renew your CE certificate, we will remove the CE aspects from your conformity assessment plan and continue to deliver UKCA conformity assessment.

If I use the abridged route to UKCA conformity assessment and my CE certificate is withdrawn, what will happen to the UKCA certificate?

As part of your contract, you are obliged to inform DQS MED UK of any changes to certification. We will take our decision as to whether the UKCA certificate should be withdrawn/suspended based on the information provided. Any changes to the UKCA certificate are notified for MHRA.

If I use the abridged route to UKCA conformity assessment and my UKCA certificate is withdrawn, can I still place product on the market of Great Britain under my CE certificate whilst CE is recognised?

Access to the UK market via CE certification is managed by MHRA. They will consider any safety or compliance issues, taking into account the reason for the withdrawal/suspension, to determine how to manage CE access.
If there is a serious safety concern, then MHRA can use enforcement powers to take action to remove the product from the UK market or prevent further supply.

FUTURE PLANS

Is there any value in UKCA marking?

The situation may depend on the type of device, as currently CE marking is accepted as a route to market.
For innovate devices and software, the MHRA roadmap indicates new approaches, potentially providing unique opportunities for manufacturers of such devices.
It is important to stress that the situation in the UK is evolving. Whilst there may always be alternative routes to market, it is only UKCA certification that offers 3rd party conformity assessment to the UK MDR and can provide the assurance manufacturers need.

When will the new UK legislation be released?

Unfortunately, we do not know exact dates, we expect this to be sometime during 2024/2025. For more information, see the MHRA roadmap.

Should you have any questions, please do not hesitate to ask us using our enquiries email box dqs-uk@dqs.de

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