UKCA for medical devices and IVDs

Frequently asked questions

bsi

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Contents

List of abbrieviations

MD	Medical Devices
IVD	In vitro diagnostics
UKAB	United Kingdom Approved Body
NB	Notified Body
AB	Approved Body
CAB	Conformity Assessment Body
EU	European Union
GB	Great Britain
NI	Northern Ireland
UKRP	United Kingdom Responsible Person
MHRA	Medicines and Healthcare products Regulatory Agency
EC REP	European Authorized Representative
UKCA	United Kingdom Conformity Assessed
DoC	Declaration of Conformity
ER	Essential Requirements
UK(NI)	UK(NI) Marking or UK(NI) Indication

Non-EU country imports

If we purchase products from non-EU countries, are we considered an importer? (Even for those products that are placed by other distributors in the UK)?

This will vary depending on your situation. We recommend you to seek legal advice on this matter.

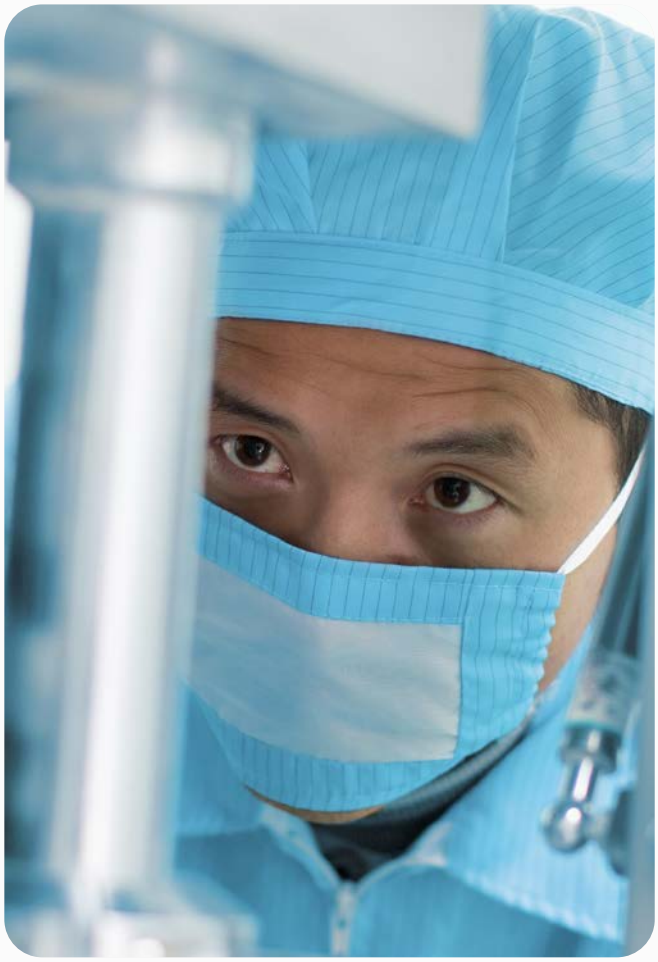
Third-party manufacturers/ consumables/supply chain

Distributors in the UK don't have any responsibilities for product compliance under the MDD. Will this continue to be the case in the UK after 26 May 2021?

Additional guidance is anticipated from the MHRA on the roles of importers/distributors.

In the UK, does the importer/distributor of products from a non-UK manufacturer have any obligation to check if the manufacturer has mandated a UK Resp. Person? If yes, can the importer/distributor access the MHRA database for checking this?

In cases where the Great Britain importer is not the UKRP, the importer is required to inform the relevant UKRP of their intention to import a medical device. In such cases, the UKRP is required to provide the MHRA with a list of device importers.



Previous obligations around storage, transportation and checking device labels for the CE or UKCA mark will continue to apply. The importer's name and address will not need to be present on the label unless the importer or distributor are acting as the UKRP for the purposes of the UKCA mark. Please refer to the **MHRA Guidance**.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Does the UK MDR 2002 have specific requirements for importers similar to the IVDR?

In cases where the Great Britain importer is not the UKRP, the importer is required to inform the relevant UKRP of their intention to import a device. In such cases, the UKRP is required to provide the MHRA with a list of device importers.

Previous obligations around storage, transportation and checking device labels for CE or UKCA mark will continue to apply. The importer's name and address will not need to be present on the label unless the importer or distributor are acting as the UKRP for the purposes of the UKCA mark. Please refer to the **MHRA Guidance**.

Can our importer (UK authorized representative) sell the medical device (only CE marked and imported before 30 June 2025) to the distributor after 1 July 2025?

If the device is already placed on the GB market, then it may be permissible to make it available to the customer after 1 July 2025. However, please confirm with MHRA or request legal advice.

Can our distributor (in the UK) sell the medical device (only CE marked and imported before 30 June 2025) to the customer after 1 July 2025?

If the device is already placed on the GB market, then it may be permissible to make it available to the customer after 1 July 2025. However, please confirm with MHRA or request legal advice.

Does UK importer information need to be present on the label?

The importer's name and address will not need to be present on the label unless the importer or distributor are acting as the UKRP for the purposes of the UKCA mark. Please refer to the **MHRA Guidance**.

Is it still possible to sell in Europe products with a UK manufacturer with old labelling if they are already in the distributor warehouse?

If the device is already placed on the European market, then it may be permissible to make it further available to the customer. However, please request legal advice.

We are a pharmaceutical wholesaler who distributes MD alongside pharmaceuticals into the EEA. Are we correct in believing that to import MD into the EEA from GB, we will need to ensure the product is CE marked, or can we distribute UKCA marked products?

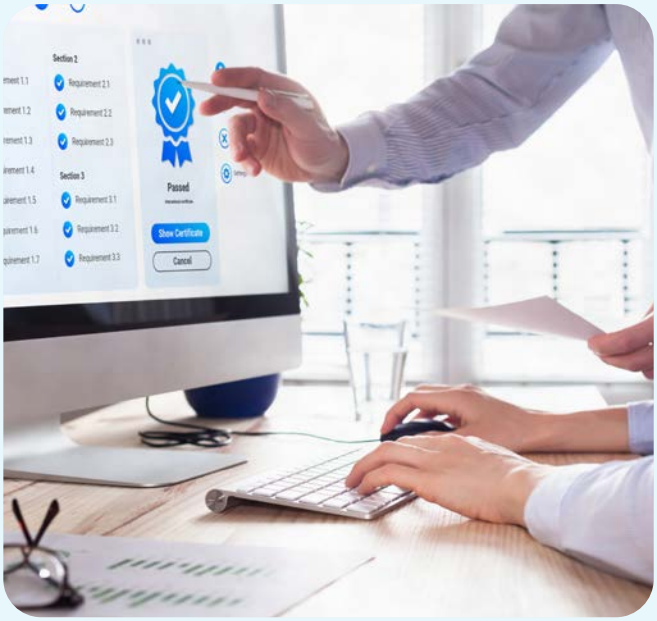
The UKCA mark is not recognized or accepted in the EEA. The products will need a CE mark as per the applicable European legislation.

Risk assessment ISO 14971

Do we need to update our technical file risk assessment to ISO 14971:2019?

The list of designated standards for the UK is available on the below websites:

- **Designated Standards Medical Devices**
- **Designated Standards AIMDs**
- **Designated Standards IVDs**



Managing inventory and labelling

Will the UKCA mark also include an Approved Body (AB) number for certain classes of devices, similar to the CE mark?

Yes. The AB number must be included if an AB was involved in the Conformity Assessments as per the ER of the Directives. The AB number for BSI UK is 0086.

Does the UKCA mark need to go on the physical device, or placing it on the label is correct if there is not sufficient space on the device itself?

It is expected that the rules that apply to CE marking as per AIMDD/IVDD/MDD will also apply to the UKCA mark as the legislations, which entered into force on 1 January 2021, are based on the Directives.

From 1 July 2025, any medical device manufacturer who places the product on the market in the UK and the EU will have to comply with the UKCA and MDR? Therefore, product labelling will have to include both the UKCA and CE mark?

Yes, both UKCA mark and CE marking would be required, but this depends on how you are placing devices on the GB market. Please also be aware of the content of the Government response to consultation on the future regulation of medical devices in the United Kingdom.

After June 2025, can we have both CE and UKCA on a label and would we need to have both AB/NB numbers on the artwork?

The definitive answer to this question will have to come from the EU. However, to our knowledge, there is no precedent of not allowing dual marking in the EU if the applicable ER are met for CE marking.

The MHRA guidance says, "Products carrying both the CE mark and UK(NI) mark cannot be placed on the EU market." Can you clarify this point?

The intention behind the combination of CE+UK(NI) mark is to identify products that are aimed at, and will be limited to, the Northern Ireland market and for which a Conformity Assessment has been carried out by a UK based CAB against ER. Hence any product with UK(NI) mark cannot be placed in the EU market.

What is the appropriate manner to refer to the UK legislation valid from January 2021 (for example, in the QMS quality manual or on a DoC)?

The legislation is the Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791), 2020 (SI 1478) and 2023 (SI 627).

Is UKCA marking required on either labelling or IFU? Not for both? How about the package?

It is expected that the rules that apply to CE marking as per AIMDD/IVDD/MDD will also apply to the UKCA mark as the legislations, which entered into force on 1 January 2021, are based on the Directives.

Will we have to update our labelling (non-UK manufacturer) after July 2025 with the UKCA mark and UKRP?

This depends on how you are placing devices on to the GB market. The transition requirements per SI 2023 No. 627 may apply, therefore UKCA marking may not be required.

Would it be allowed to add a sticker to the outer sales packaging with both the UKCA and UKRP but as a separate label to the product label like a controlled additional product label without of course over labelling any information from product label?

As long as the ER for labelling are met as per the legislation this may be possible.

What about stock in companies' warehouse, made 3 years ago showing CEXXX. Can it be sold after July 2025 without relabelling?

This depends on whether requirements listed in SI 2023 No. 627 are met.

Transition Timelines

What are the new timelines for CE marking acceptability in the UK?

Please refer to our dedicated UKCA marking **webpage** and to our **UKCA Roadmap**.

If the manufacturer introduces a new product under the EU MDR after 1 January 2021 and before 1 July 2025, can this be sold in the UK with CE marking or will conformity with UK legislation (UKCA) be required?

The exemption will apply to devices CE marked even after 1 July 2025, but only until 30 June 2030.

UKCA Certificate is issued based on the 93/42/EEC. Are we going 18 years back?

Directives will be in effect immediately from 1 January 2021. However, the intention of the UK Government is to publish secondary legislation via the Medicines and Medical Devices Act of 2021 that will introduce a new regulatory framework.

If there's a medical device that falls under the MDD and another legislation (e.g., PPE). The transition timelines for UKCA marking are different. In your opinion, which timeline would take precedence?

It has been clarified that the longer of the transition timelines will apply. So, in the example above, such products that qualify as both PPE and MD will have until 30 June 2025, after which UKCA marking becomes dependent on the requirements of SI 2023 No. 627 and the new UK legislation.

From 30 June 2025, do you think it will be mandatory to recall MD still placed on the GB market with an EU MDD Certificate?

No. However no new devices can be placed on the GB market from 1 July 2025 without the UKCA mark, unless requirements under SI 2023 No. 627 are met.

If we want to apply the UKCA mark on Class I devices while doing a packaging change, can we? Do we need a new DoC?

The UKCA mark applies from 1 January 2021, and if conformity has been established with the UK legislation, then the DoC must be issued against the UK legislation, and then the UKCA mark applied.

How long will a UKCA Certificate be valid for?

Until the new legislation is published we cannot say how long current certificates will be valid for as this could change due to the transitional arrangement. For now BSI is issuing new certificates with a 5 year validity, however these may be cut short due to the transitional arrangements.

For identical devices that are placed on the market in NI, in addition to Great Britain and Europe, would it be acceptable to be CE marked using an EU NB and UKCA marked by a UKAB, with labels and DPM showing CE and UKCA together on the device?

Yes, if placing devices onto UK and NI market then dual marking with CE and UKCA marking is allowed. This does not need to be done by an UKAB who is also an EU NB, these can be two separate bodies.

Can products which are legacy inventory (which is already in the UK at a distributor that only has CE marking) continue to be sold post 1 July 2025? Or do they need to be destroyed/recalled?

It depends on whether these devices have already been placed on the market before the timelines stated in SI 2023 No. 627. If so they can be, if not they cannot, be placed on the market.

What is the renewal process for UKCA marking, thinking of the situation where we use MDD to get UKCA mark and therefore have a short expiry, UKCA renewal would be needed very quickly?

Yes, a renewal would be required as per the usual ER where we review the past 5-year cycle therefore all surveillance audits for technical and QMS would have to be completed before the renewal.

A client received pushback for labelling a product with both CE and UKCA marks after it was properly registered with the MHRA per the ER. Is this because the UKCA mark can only be applied after 1 January 2021?

The UKCA mark entered into force on 1 January 2021 and can only be applied if the UKCA requirements have been met, including having a certificate (if required) from a UKAB and registering with the MHRA.

You mentioned how changes to an EC Certificate would prompt re-issuing as a UKCA Certificate. Are we saying that an equivalent rule to MDR Article 120 on significant changes applies to EC Certificates after 1 January 2021?

CE certificates issued by UK NBs prior to 1 January 2021 will continue to be valid for the GB market. On 1 January 2021, UK NBs became UKABs. UKABs cannot issue or re-issue CE certificates. They can only issue or re-issue UKCA certificates; therefore, any changes to CE certificates (originally issued as EU NB) after 1 January 2021 will need to be processed as UKCA certificates. The criterion for what constitutes a substantial change will be as per the applicable Directive ER depending on the route to conformity followed.

If the MDR and IVDR doesn't apply to GB, will GB still accept a product approved under the MDR until June 2030?

Yes, that is correct; GB will accept devices CE marked devices under IVDR/MDR until 30 June 2030.

"Established compliance with UK MDR 2002" means we have to be assessed by BSI prior to using the UKCA mark?

Depending on the classification of the medical device, a UKAB assessment will be required before a UKCA Certificate can be issued based on which the device can be UKCA marked.

Would the MHRA adapt the MDR rules, or will it continue to comply with the MDD rules? The same question applies to IVDR vs IVDD?

MHRA accepted Amending Reg. (EU) 2023/607 for CE transition timelines of Directives devices.

If an EC certificate is transferred from another NB, will the expiration date on the EC Certificate count for the UKCA Certificate, or the UKCA Certificate will be issued with a new expiration date? What will be the expiration date?

UKCA Certificates issued based on other EC Certificates will retain the expiry dates of the original EC Certificates.

Is it possible to ask for UKCA certification just before the MDR Certificate process is initiated by BSI?

There are several factors to consider about the timing of UKCA certification when there is an ongoing MDR CE application. Please speak to your Scheme Manager for further clarification.

Under MDD CE we can't make significant changes (due to the transition to MDR). If we get a UKCA mark based on the MDD CE mark, can we then make significant changes even if we have not completed the MDR CE transition?

Yes. You can as you are making the changes under the UK legislation once you have a certificate for UKCA and the devices are placed on the market under the UK MDR 2002 for the UK market. The transitional arrangements for MDD are only in place for devices placed on the EU market.

MHRA Registrations

Do we need to register medical devices that have an expired CE certificate that is valid under EU Directives?

In March 2023, the EU revised the EU MDR transitional arrangements to extend the validity of EU MDD and EU AIMDD CE certificates in limited circumstances for certain medical devices. These devices would need to be registered as per **MHRA Guidance**.

How do we register with the MHRA?

Information on registering MD is available on the **MHRA website**.

A medical device certified under BSI NL and marketed in the UK, should have on the labelling the UKRP?

In the case of MD placed on the GB market based on CE certification / CE marking, manufacturers outside the UK must appoint a UKRP, but it is not mandatory to identify a UKRP on labelling.

Do we have to wait for the UKCA audit to be passed before registering our devices?

This depends on the classification of the medical device and also whether you are placing the device on the market using your CE mark until the transitional arrangements per SI 2023 No. 627. If you are, then a UKCA assessment would not be required. If you are not using CE marking to place the product on the market, a UKCA assessment would be needed before registering the device.

If a manufacturer has a CE mark issued by a NB other than BSI, can it supply the device to the UK until June 2025?

Yes, however, devices will need to be registered with the MHRA as per **MHRA Guidance** on regulating MD in the UK.

If devices are already registered with the MHRA for CE marking, does the UKCA require any additional registrations if we are in the UK?

Information on registering devices is available on **MHRA Guidance** on registering MD to be placed on the market. For MD that are already registered with the MHRA, manufacturers are required to re-confirm the device details.

Are registrations per GMDN code?

Information on registering devices is available on **MHRA Guidance** on manufacturers registering to sell MD.

UKRP

If a company has multiple distributors in the UK, will each be required to list a UKRP, or just one?

Only one UKRP is required.

Has the MHRA made available the registration portal where a manufacturer can start registering their products, or should the UKCA legislation be passed before the MHRA can publish this registration portal?

Information on registration of MD is available on **MHRA Guidance** on manufacturers registering to sell medical devices. It is anticipated that further guidance will be published on the registration of devices.

Can the UKRP be an organization, or does it need to be an individual?

It can be an organization similar to the EC REP.

Is a letter of delegation required for the UKRP? Or is an agreement required as per ER requirements?

The requirements are expected to be similar to those that apply for EC REP.

As a UKRP, do they need physical 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 DoC, and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA.

Will the UKRP also be in charge of vigilance reporting, or will this remain with the manufacturer outside the UK?

The guidance from the MHRA states: "Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated".

Are there any qualifications needed to be a UKRP?

The MHRA guidance does not provide any information on the qualifications needed for a UKRP. However, it would be expected that they are qualified enough to conduct the activities expectant of them.

Does the UKRP need to comply with any qualification requirements (e.g,. BSc) or nationality (e.g,. UK national or just UK address)?

No requirements have been set related to this. However, it would be expected that they are qualified enough to conduct the activities expectant of them.

If MD are being virtually manufactured in the EU, but the legal manufacturer is based in the UK, does the virtual manufacturer need to have a UKRP?

The legal manufacturer has the responsibility as they are placing the device on the market; if the legal manufacturer is based in the UK, they do not need a UKRP; only legal manufacturers outside of the UK need a UKRP.

Does the UK MDR 2002 require the UKRP to verify the technical documentation and DoC of the Legal Manufacturers?

Please refer to the **MHRA website** for responsibilities of the UKRP.

If we are a UK manufacturer, to place a product on the EU market, do we have to appoint an EC REP who will be based in the EU?

Yes, as the UK is no longer in the EU, manufacturers outside the EU require an EC REP based in either the EU or NI.

UKRP information needs to be included in the labelling. Does this mean product label or Instructions for Use or both?

For devices with the UKCA mark, manufacturers outside the UK must appoint a UKRP and identify the UKRP on either the labels or IFU.

What are the legal responsibilities and liabilities of the UKRP?

Information on responsibilities of the UKRP is available on the **MHRA Guidance** on regulating MDs in the UK.

Is there a grace period for registering a UKRP?

Information on this is available on the **MHRA Guidance**.

Only one UKRP is allowed per legal manufacturer. Can you confirm this is per article/device?

This is based on feedback BSI received from the MHRA that a manufacturer should appoint only one UKRP for all their devices.

Has an agreed symbol been defined to represent the UKRP?

No agreed symbol has been published at this time.

A UKRP must be identified on either labels or IFU. Can it be only on one of the two, or does it need to be on both?

For devices with the UKCA mark, manufacturers outside the UK must appoint a UKRP and identify a UKRP on either the labels or IFU or both.

If a company is based in the UK but a part of its manufacturing facility is in the US, a UKRP must be identified and based in the UK?

UKRP must be based in the UK.

When the product is labelled with a CE and UKCA mark, both EC REP and UKRP should also be labelled?

Yes.

If the UKRP is a homebased employee, does their home address or employer address get listed on the label?

If the company is registered there then yes, but the UKRP does not have to be a individual person it can be a company as well, similar to the principles of an EC REP.

In the case of having a CE marked Drug Device Combination where it is classified as medicine, shall the UKRP information be included in the label?

According to EU Medicine Legislation, this is not allowed.

Will the MHRA accept drug consultations from other competent authorities issued as part of the EU MDR certification? Will the MHRA insist on a review of the medicinal dossier?

This is on a case by case basis and we will consult with the MHRA once you apply.

Associated regulations and standards

For laboratory instruments that are not IVDs, but general-purpose and have a CE mark in accordance with the Low Voltage Directive or Machinery Directive, what will be the requirements in the UK?

Please refer to the **UK Government's guidance** on the relevant legislation.

What are the arrangements/plans for UKCA marking for the replacements for EU Directives (e.g,.EMC, RoHS3, Low Voltage) from January 2022. For instance, a medical device power supply would be covered with the above EU Directives.

Please refer to the **UK Government's guidance** on the relevant legislation.

If a medical device also needs to meet the RoHS Machinery Directive, what deadline needs to be met for the UK marking?

Recent guidance indicates that the longer of the two deadlines will apply.

Alongside the MDD/MDR, we have compliance to the EU Radio Equipment Directive, too (e.g,.wireless hearing aids). We need to comply with UK Radio Regulations by January 2022. Will we need to affix a UKCA mark to products before we have applied for the UK MDR compliance?

Recent guidance indicates that the longer of the two deadlines will apply.

If I have a CE marked device, then I want to apply for UKCA. Do I need to amend all references within my technical documentation to UK regs/standards?

Yes. The technical documentation must refer to UK legislative references, including designated standards, as applicable.

Must the labeling for UK bear the UDI as it is compulsory for MD now due to MDR?

UDI is mandatory for EU. However, UK legislation does not require this to be mandatory.

Is it acceptable to use a newer version of a standard where this is not reflected in the UK designated list, i.e., ISO 14971 2019 vs 2012?

Please follow the same principles you are using in the case of CE marked devices.

Will adding another paragraph to cover UKCA in our DoC be sufficient?

As long as ER related to a UKCA DoC are fulfilled this should be sufficient.

EU/GB/NI

Will UK NBs still offer the CE mark route under MDR post 1 January 2021?

No. UK NBs will become UKABs and will be able to conduct Conformity Assessment for the UK legislation. As an exception, UKABs, which are designated to MDR/IVDR, can also conduct Conformity Assessments against the MDR/IVDR for the NI market. In such cases, the manufacturer would have to apply a UK(NI) mark along with the CE mark. Such devices will have to be limited to NI.

What would be better for a small R&D company, go straight for CE marking, or attempt to comply with both CE marking and UKCA ER?

It depends on your most important market, an EU Regulation certificate will be valid until 30 June 2030.

From January 2021, only an MDD DoC will be accepted in GB? If yes, for Class I devices the manufacturer needs to keep an MDD DoC only for the GB market?

Devices CE marked via self-certification will be accepted in the UK as per **MHRA Guidance**.

We are registered with BSI The Netherlands, which covers both UK and EU market. Will we have to dual mark our devices?

CE marked devices will be accepted in the UK until the transitional arrangements outlined in SI 2023 No. 627. In order to apply the UKCA mark, devices need to undergo a UKCA Conformity Assessment process.

Can a UKAB for a manufacturer in the UK approve products for sale in the EU with a CE mark, or do we need two different ABs/ NBs?

UKABs cannot conduct Conformity Assessment for EU CE requirements. Only EU NBs can conduct Conformity Assessments against the EU requirements. BSI already operates as both, as an EU NB (BSI NL 2797) and UKAB (BSI UK 0086) from 1 January 2021.

Is the Republic of Ireland under the UK MDR 2002 or under the EU MDR?

The Republic of Ireland is part of the EU, so CE marking under the EU MDR will be applicable.

To add UK(NI) mark might result in EU rejecting a product? On the contrary, NI will accept a product without the UK(NI) mark?

Information related to placing devices on the Northern Ireland market is available on **MHRA Guidance** on regulating MDs in the UK. Devices bearing the UK(NI) mark cannot be further circulated into Europe after being placed on the UK(NI) market.

Manufacturers will have to face an audit also for the UK(NI) mark or a single audit for the CE mark will cover both?

Information on placing devices on the NI market is available on **MHRA Guidance** on regulating MDs in the UK. CE marking is valid in Northern Ireland if the assessment is carried out by an EU NB.

How should technical documentation be addressed in order to cover both EU MDR and UK MDR 2002 ER?

It is up to the manufacturer how they address this requirement. Separate technical documentation or a combined technical documentation that covers both the ER. In the latter, clear organization of the information within the file is critical.

How do we handle grace periods and other issues that will appear with MD that are classified differently according to the GB and the EU?

For GB, follow the classification of devices as per the UK legislation UK MDR 2002, which is based on the Directives.

When CE and UKCA marks are achieved, will reporting significant changes be streamlined to both CABs?

BSI has streamlined its processes. In such cases, one change notification form can be submitted towards both the legislations.

Does the EU MDR technical documentation meet the UKCA requirements, or is there a separate/specific UK technical documentation required for the UKCA?

In general, the MDR ER are over and above the requirements of the UKCA, which is based on the EU Directives. However, it is key that manufacturers show compliance to the applicable ER clearly against the applicable legislation.

Regarding technical documentation under UKCA assessment, can we use our EU technical documentation and integrate UKCA specific ER for both?

It is up to the manufacturer how they address this requirement. Separate technical documentation or a combined technical documentation that covers both the ER. In the latter, clear organization of the information within the file is critical.

For Combined Applications, the UK website requests separate technical files for UK and EU. Should we create two different files to be submitted for review?

As long as your technical documentation references UK legislation for the relevant part, this can be one technical file.

Our MDD Certificate is valid until April 2024, and we have associated audits scheduled this year. How will these scheduled audits be impacted (combined?) for assessments based on acceptance of our application for UKCA?

If your UKCA Certificate is issued prior to your assessments we will combine the audits. Once the UKCA Certificate is issued they are put into contract so all legislations are covered when possible to do combined reviews.

If we are leveraging MDR CE Certificate or if we are applying for UKCA at the same time as the EU MDR application, would we need to classify the medical device according to the MDD or would the classification under the MDR be sufficient?

Classification needs to be carried as per the UK MDR 2002 as this is the legislation you are claiming compliance to.

As part of the UK top-up assessment, do we need to also provide evidence of compliance to the ER as per Annex I of MDD or would compliance to Annex I of EU MDR be sufficient?

Evidence on meeting the ERs will be needed as this is how ER of the UK MDR are met, some may overlap however you must show compliance to UK MDR 2002.

What clinical evidence will be required to approve non-CE Class IIa products and could predicate testing and data (i.e., 510k similarity) be used?

You must meet the ER as detailed in the UK MDR 2002, which is equivalent to Annex X of MDD.

CE Certificates under MDD are accepted until 30 June 2025, but what happens if this certificate expires before this date? Do we need to also obtain the UKCA Certificate before 30 June 2025 or will CE certificates under MDR be accepted?

Please refer to **MHRA Guidance** on reliance on expired/expiring CE certificates under MDD/AIMDD.

For CE route in NI, can a UKAB assess conformity to European legislation?

UKAB can apply with the MHRA to be designated under the relevant EU legislation for the purposes of conducting Conformity Assessments for the NI market only.

If UKCA and CE marks are applied on the device together, do we need to be audited by the same NB?

Not necessarily. A manufacturer can choose to work with a different EU NB and a UKAB. However, this could lead to extra audits and assessments that may be avoided by having the same CAB serve as both the EU NB and UKAB.

We have a CE (2797) Certificate and planning to apply for UKCA (0086) assessment. Will unannounced audits be conducted on both respectively after receiving the certificates?

BSI will try and combine unannounced audits wherever possible so a single audit can cover both the legislations. However, this cannot be guaranteed and will depend on many factors.

Are UK manufacturers able to self-declare a Class I device with a CE mark?

Devices CE marked via self-certification will be accepted in the UK as per **MHRA Guidance.**

Will CERs written for the MDR be acceptable for UKCA?

It is plausible. It is up to the manufacturer to show that the ER of both the legislations have been met.

If a manufacturer is seeking to market a new device in the UK without any prior certifications (for company or device), is the manufacturer required to pursue the UKCA pathway? Or can it pursue the CE mark and market in the UK until 2025?

The latter approach is possible.

In our QMS, can we maintain references to the MDD, or will we need to update by 2025 to reference the UK regulations?

QMS should refer to the UK legislation when the manufacturer establishes compliance to the UK legislations.

If the UKCA is granted according to the MDR 2002 after the new Medical Bill is approved, do we need to change any aspects of the technical documentation according to the new law?

It will depend on what the new legislative framework requirements will be.

Risk Class Queries

For Class I MD, will the UKCA mark be recognized on the EU worldwide pack with a CE mark after June 2025? Or will the UK need a separate pack with the UKCA mark?

Dual labelling with a UKCA and CE mark will be permitted in the UK.

A legal manufacturer of Class IIa MD based in the UK, with BSI as NB and having transitioned to BSI NL (CE 2797) can continue to place its devices on the UK market until 30 June 2025 before having to comply with UKCA labelling requirements? How do these requirements translates to device accessories?

Accessories to MD are treated as MD themselves. So, the same rules apply to accessories as well.

Is there any guidance on competent authority approval requirements for combination devices under MDD Annex I, point 7.4 for UKCA certificated devices?

The requirements would be expected to mirror those of the current consultation requirements under the MDD.

Depending on its classification, to continue being sold in the EU, a product must comply with the MDR. If the same product is sold also in the UK, will a MDR Certificate be required, or the product can remain on an MDD cerificate to obtain the UKCA mark?

If the intention is to just sell in GB, then the manufacturer has the option to just consider the UKCA ER. However, please note that Northern Ireland will continue to operate under EU rules, and hence MDR will apply in Northern Ireland from 26 May 2021.

Can a manufacturer self-certify Class I devices? Is a UKCA certification needed?

Manufacturers of Class I MD and general IVDs can self-declare their conformity against the UK MDR 2002 (in the form in which they existed on 1 January 2021) before affixing a UKCA mark and placing the device on the Great Britain market.

Class I MD that are sterile or have a measuring function require approval from the UKAB in order to be affixed with the UKCA mark and placed on the Great Britain market?

Please refer to **MHRA Guidance** on regulating MDs in the UK.

Do we now need to register each custom-made device with the MHRA and seek their approval?

Refer to **MHRA Guidance** on registrations.

Do you have information on whether an Article similar to the EU MDR Article 117 is under preparation for UK MDR?

There is no equivalent under the UK MDR 2002. It may be included in the future legislative framework for the UK.

For Class I MD, when/how should we apply UKCA?

Such MD can be self-certified against the UK MDR 2002 legislation.

Can a manufacturer of self-declared/ General IVDs place the UKCA mark on the products from now on?

Yes, as long as compliance has been established with the UK MDR 2002 as amended by EU exit legislation.

Do all devices need to undergo Conformity Assessments prior to July 2025? Is there any grandfathering?

It is unknown at this time.

Regarding custom made devices, in the case of 'customized procedure packs', will each integration need to be registered individually?

Refer to **MHRA Guidance** on registrations.

Do you have any insight into whether drug-device consultations between the MHRA and a European NB will continue to be valid for devices already bearing the CE mark before January 2021?

The UKAB will have to establish that the previous consultation remains valid considering device changes etc. and confirm with the MHRA if the consultation needs to be repeated.

Will any of the current regulatory ER for custom-made devices change after 30 June 2025?

Unfortunately it is hard to say until the new legislation is published.

The name of the UKRP will be the legal entity name rather than the name of an individual person?

That is correct, it is similar to that of an EC REP.

Do manufacturers of Class I MD need to appoint a UKRP?

If a manufacturer is outside of the UK a UKRP will be required regardless of classification.

Can the scope of the UKCA Certificate be smaller than the previous EC certification?

Yes, the proposed scope of the UKCA Certificate can be smaller than the one of the EC certificates.

How can a device with no medical purpose and not covered by the scope of the MDD be certified under UKCA?

Devices without a medical purpose are not covered by the scope of the MDD, therefore they cannot be certified under UKCA.

BSI Procedures

Under the IVDR/MDR, NBs have to avoid consultancy with companies. Do you think this will be the case for UKABs?

NBs must avoid consultancy with companies even under the Directives. The IVDR/MDR strengthened those requirements.

Will future surveillance audits from BSI require a separate UK-focused regulatory compliance audit, or would they be combined with existing MDD-MDR/ISO audits?

Audits will be combined wherever possible. A small increase in audit durations may need to be considered to cater for the number of different legislations being covered in the audit.

What UKAB number is to be included in case a UKAB has been involved in the Conformity Assessment?

The UKABs retained their EU identification number (0086 for BSI UK).

To meet the UKCA mark, will BSI follow the same process under the IVDD, so the same classification rules will apply and not the new IVDR classification?

That is correct as per UK MDR 2002 Part IV, which is available on the **UK Government webpage**.

Can our BSI NL account manager liaise with BSI UK to organize our UK audit?

Yes, they will be able to support you.

Does BSI UK consider Conformity Assessments by NBs other than BSI NL?

Yes. BSI will apply an abridged Conformity Assessment process that is very similar to the Transfer process.

Can we have one common technical documentation covering UK MDR 2002 and MDR/MDD, or does BSI expect to have separate technical documentation? If the review is combined, the manufacturer can combine documentation too?

It is up to the manufacturer how they address this requirement. Separate technical documentation or combined technical documentation that covers both the requirements. In the latter, clear organization of the information within the file is critical.

Who will be the NB that issues the certificates, or can we have both 0086 and 2797 on the certificates, such that we can have UKCA as well as we can benefit from Taiwan's TCP scheme?

BSI NL (2797) will issue certificates for the European legislations. Separate stand-alone certificates will be issued by BSI UK (0086) for the UK MDR 2002 legislation.

If we transfer a CE Certificate to a UKCA Certificate, what would the expiry date on the certificate be?

If a UKCA Certificate is issued based on a CE Certificate, the expiry dates will be aligned.

For an initial application for both UKCA and CE, who should the application be for, BSI UK or BSI NL, or do we need to apply both?

A single application that covers both legislations submitted to both BSI UK and
BSI NL.

Will BSI provide a gap assessment comparing the UK MDR 2002 and the EU MDR?

BSI, in its role as a NB or UKAB, cannot provide any form of gap assessments.

Have the UKABs started assessing the technical documentation and issuing UKCA certificates?

Yes.

Being a BSI client, does this imply that the company automatically is a client for BSI UKNB, or do we need to apply?

A separate application is required for UKCA certification.

If we have a new device that we want to market with a CE mark (via BSI NL) and a UKCA mark (via BSI UK) at the same time, will BSI be able to consolidate audits/ assessments for both CE and UKCA marking?

Yes, BSI will combine assessments wherever possible.

Does the UKAB need to undertake full assessment for devices with CE mark when applying for UKCA Certification?

Currently not, if you are issuing a UKCA Certificate on the basis of EU certification you may not need a full assessment.

We submitted separate applications for both the MDR and the UKCA. Will BSI automatically make it a combined application and conduct the assessments at the same time?

You must inform your Scheme Manager if you would like to combine these so the quotations can be amended accordingly.

Could you clarify what you mean by follow the transfer process in case of a UKCA application to BSI by a manufacturer holding MDD or MDR CE mark from another NB? Does it mean the manufacturer needs to transfer all its CE mark MDD or MDR to BSI?

No. It is not mandatory to transfer all certification to BSI however we will carry out the same transfer process we do when we transfer other certification.

Can BSI UK support us for UKCA certification even if we have a different EU NB for EU CE certification?

Yes, we can issue the UKCA certification based off other EU NB certification.

NBs are often recommending a regulatory consultant to be hired for assistance with submissions when these have failed. What credentials will the NB be looking for in relation to those consultants and what are the means by which EU MDR consultants can best obtain those credentials?

BSI cannot and will not recommend any consultants to manufacturers this is up to you as the manufacturer to make the decision whether one is needed or not.

For EU-based manufacturers wanting to perform a combined Conformity Assessment for CE and UKCA marking, is contact with BSI NL (2797) sufficient for both or does a contact also need to be established with BSI UK (0086)?

Our resource is shared amongst the NB and AB therefore you can use your same contact at BSI if you wish to apply for UKCA certification.

Will BSI UKAB and BSI NB unannounced audits be run in parallel thus keeping costs and time lost low for the manufacturer?

Where possible we will combine assessments for both legislations.

QMS / ISO 13485 / MDSAP

Will companies need both a CE Certificate and a Quality Certificate to be on the Great Britain market?

The GB market will accept CE certificates until 30 June 2025 and, for certain medical devices, beyond this date if the requirements of SI 2023 No. 627 are met. If the question is referring to ISO 13485 certificates as Quality certificates, then these are not mandatory for accessing the GB market.

Assuming UK regulations continue on MDD basis for some time, how will BSI (0086) consider the QMS aspects given most manufacturers will have moved to MDR Conformity Assessment (and not have Annex II.3/V). Will there be recognition of ISO13485/ MDSAP for UKCA, or will there be UK-specific QMS audits of legal manufacturers? Will the UKRP be audited (and by whom)?

While there are a few differences in the Quality Management System requirements between the Directives and Regulations, they are largely similar and based on the standard ISO 13485. Technical documentation must show compliance to the UK legislation UK MDR 2002 to apply the UKCA mark. For the UKRP, during manufacturer audits, BSI will audit the qualification process, the appointment of the UKRP and the agreement between the manufacturer and the UKRP. The UKRP itself is unlikely to be audited unless there are specific reasons for this to be completed.

Are you able to combine an MDSAP audit with a UKCA audit?

Yes. QMS audits can be combined however additional time may be needed to cover multiple legislations.

Does it mean that if we already have a MDSAP certification it will be recognised by a UKAB, and we could get a certificate without any reviews?

No. Currently additional reviews for UKCA would be required.

Is a UK QMS audit required in addition to technical documentation review before issuing the UKCA Certificate? What if we already have a successful EU MDR QMS?

If you do not have any issued EU certification an additional QMS assessment may be required when applying for UKCA. If following the abridged process (issuing UKCA certification on the basis of EU certification) then initial QMS assessment would not be needed for certificates issued by BSI.

Is having an ISO 13485 from a European NB acceptable towards a UKCA mark or would a re-audit of the QMS system be required?

Additional QMS audit time may be required to cover UK requirements, however some reductions may be possible for audit durations.

IVD Specifics

If a General IVD is already placed on the UK market, there is no grace period for registration with the MHRA. What does it mean in practice? Will the registration automatically roll over, or should we register our IVD on 1 January 2021 and no later?

Such IVD should have already been registered with the MHRA as per the current ER.

Currently, COVID-19 test devices, and their accessories, for self-test home use must go through the MHRA by derogation rather than NBs. Will BSI be in a position, as UKAB, to certify these devices to the UKCA (against the Directives) for home use from January 2021?

BSI will be able to conduct a Conformity Assessment only if the legislations require us to do so.

If currently, the IVD devices are self-certified, will they continue to be self-certified in GB after 1 January 2021 under the IVDD until 26 May 2025?

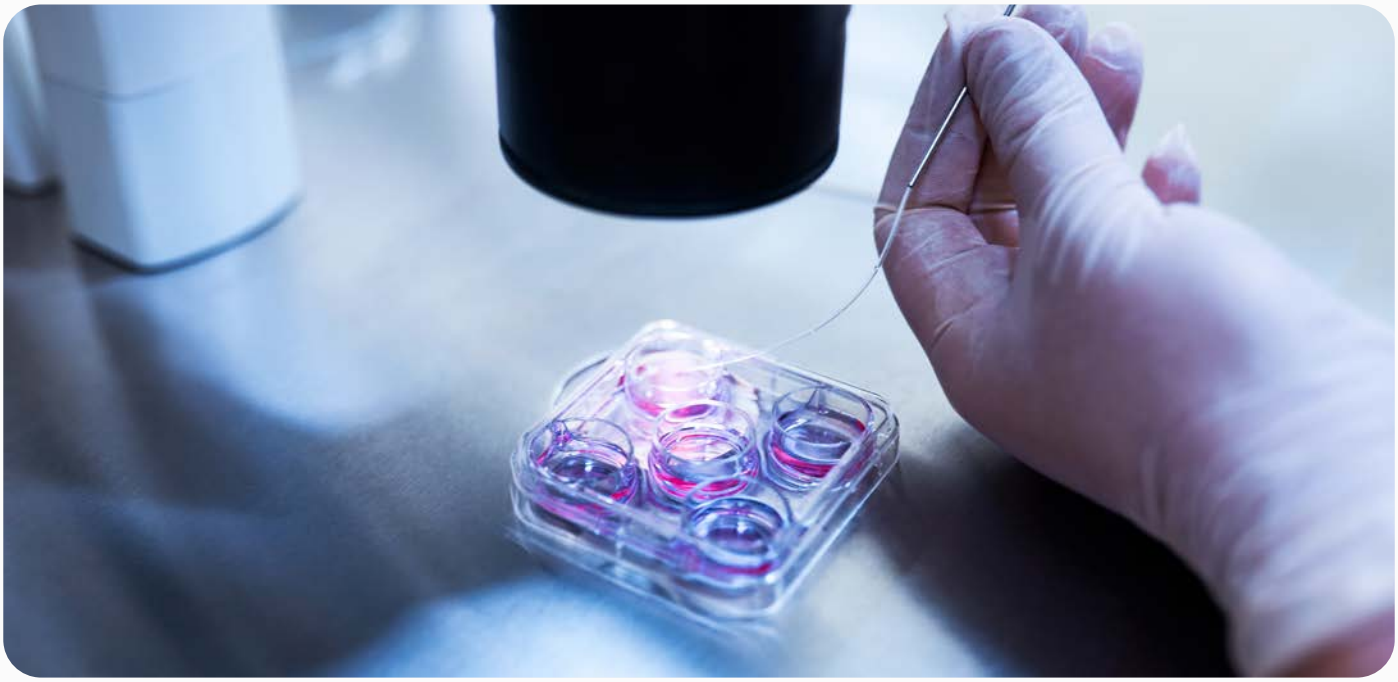
Please refer to **MHRA Guidance** for self-certified IVD devices.

We have been certified by BSI NL (2797) under IVDD and are on the way to be certified under IVDR. We are now applying for UKCA certification. Would that allow us to profit from the abridged process even though we would be IVDR certified by the time we would be audited for UKCA Certificate?

The IVDR is not aligned fully with the UK MDR 2002; therefore, it may be difficult to carry out a full abridged process. It may require additional reviews due to IVDR not being fully aligned with IVDD which has been incorporated in the UK legislation.

If doing a combined IVDR/UKCA IVDD review, would the IVDR and IVDD reviews be conducted at the same time? How long would these reviews be?

This is on a case by case basis where possible we would try to combine reviews however, due to the divergence in both legislations this may not be possible.



What will be the pathway for List A batch release with a UKAB?

We are currently in discussions with the MHRA in relation to the reference laboratories for List A devices.

In the current MHRA guidance, it is said that General IVD manufacturers will be able to self-declare their conformity with part II to IV of the UK MDR 2002 and place the UKCA mark after 1 January 2021. Is it expected that this "General IVDs" class will be related to a classification similar to the IVDD one, even after the IVDR Date of Application?

The IVDR does not apply in GB. So, the reference to general IVDs is as per the IVDD.

Does the registration requirement in UK also apply to IVDs or it is only applicable for MD?

Please refer to the **MHRA Guidance** for the list of IVDs to be registered.

Does the recognition of the CE mark also include IVDs or only MD?

CE marked devices will be accepted on the Great Britain market until 30 June 2025 and, for certain MDs and IVDs, beyond this date if the requirements of SI 2023 No. 627 are met. This applies to IVDs and MDs that have been CE marked under, and fully conform to, the following applicable EU legislation:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)
- Regulation 2017/745 on medical devices (EU MDR)
- Regulation 2017/746 on in vitro diagnostic medical devices (EU IVDR)

Can both CE and UKCA markings appear on the same IVD?

Yes, if the device complies with both the legislations.

Future Plans

How would changes be managed after initial certification? Do you expect UK to follow MDD rules to a certain extent? Would the assessment be combined if a manufacturer holds MDR and UKCA with BSI?

BSI will try to combine assessments for all applicable legislations where possible.

When will the new UK legislation be released?

Unfortunately, we do not know exact dates, we expect this to be sometime during 2024.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Your partner in progress

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