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Taking devices to market in Great Britain POST BREXIT

UKCA for Medical Devices and IVDs

FAQ Webinar 2021

UKCA for medical devices and IVDs

Webinar FAQs May 2021

1. Non-EU Country Imports

Q: If we purchase products from non-EU countries, are we considered an importer? (Even those products that are placed by other distributors in the UK)?
Not for BSI to answer. Request legal advice.

2. Third-Party Manufacturers / Consumables / Supply Chain

Q: 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.

Q: Does the importer/distributor in the UK of products from a non-UK manufacturer have any obligation to check if the manufacturer has mandated a UK Rep Person? If yes, can the importer/distributor access the MHRA database for checking this?
In cases where the Great Britain importer is not the UK Responsible Person, the importer is required to inform the relevant UK Responsible Person of their intention to import a medical device. In such cases, the UK Responsible Person is required to provide the MHRA with a list of device importers.

Other than the above requirement, there are no additional obligations on distributors or suppliers of medical devices. 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 UK Responsible Person for the purposes of the UKCA mark. Please refer to the MHRA website (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain).

Q: Does the UK MDR 2002 have specific requirements for importers similar to the IVDR?
In cases where the Great Britain importer is not the UK Responsible Person, the importer is required to inform the relevant UK Responsible Person of their intention to import a device. In such cases, the UK Responsible Person is required to provide the MHRA with a list of device importers.

Other than the above requirement, there are no additional obligations on distributors or suppliers of medical devices. 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 UK Responsible Person for the purposes of the UKCA mark. Please refer to the MHRA website (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain).

Q: Can our importer (UK authorized representative) sell the medical device (only CE marked and imported before 2023-06-30) to the distributor after 2023-07-01?
If the device is already placed on the GB market, then it may be permissible to make it available to the customer after 2023-07-01. However, please confirm with MHRA or request legal advice.

Q: Can our distributor (in the UK) sell the medical device (only CE marked and imported before 2023-06-30) to the customer after 2023-07-01?
If the device is already placed on the GB market, then it may be permissible to make it available to the customer after 2023-07-01. However, please confirm with MHRA or request legal advice.

Q: Do manufacturers need to list UK importers?
The importer's name and address will not need to be present on the label unless the importer or distributor are acting as the UK Responsible Person for the purposes of the UKCA mark. Please refer to the MHRA website (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain).

Q: 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.

Q: We are a pharmaceutical wholesaler who distributes medical devices alongside pharmaceuticals into the EEA. Are we correct in believing that to import medical devices 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.

3. Risk Assessment ISO 14971

Q: Do we need to update our tech file risk assessment to ISO 14971:2019?
The list of designated standards for the UK is available on the below websites:

- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950183/ds-0034-21-medical-devices-notice.pdf
- https://www.gov.uk/government/publications/designated-standards-active-implantable-medical-devices
- https://www.gov.uk/government/publications/designated-standards-in-vitro-diagnostic-medical-devices

4. Managing Inventory and Labelling

Q: Will the UKCA symbol also include a Notified Body (NB) number for certain classes of devices, similar to the CE mark?
Yes. The Approved Body (AB) number must be included if an Approved Body was involved in the conformity assessments as per the requirements of the Directives. The Approved Body number for BSI UK is 0086.

Q: Does the UKCA mark need to go on the physical device, or is placing on the label OK 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.

Q: So, from 1 July 2023, any medical device manufacturer who puts the product on the market in the UK and the EU will have to comply with the MDR and UKCA? Therefore, product labelling will have to include both the CE and UKCA mark.
Yes.

Q: After June 2023, 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 EU requirements are met for CE marking.

Q: The MHRA guidance says, "Products carrying both the CE mark and UK(NI) mark cannot be placed on the EU market." Would you be able to clarify this?
The intention behind the combination of CE+UK(NI) mark is to identify products that are aimed at, and will be limited to, the NI market and for which a conformity assessment has been carried out by a UK based CAB against EU legislative requirements. Hence any product with UK(NI) mark cannot be placed in the EU market.

Q: What is the appropriate way 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) and 2020 (SI 1478).

Q: 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.

Q: Slide 14 states a 6-month max transition period for labelling. Given the fact that many companies use a global pack, this transition period might be too short. Is there a possibility to have more flexibility here? As the global labelling can only display the UKCA symbol once the certificate is available, this is really a challenge.
Please speak to your BSI Scheme Manager.

Q: Will we have to update our labelling (non-UK manufacturer) after July 2023 with the UKCA mark and UK Responsible Person (maybe I misunderstood one of the first slides)?
UKCA marking will be mandatory from July 2023 to access the GB market. Identification of the UKRP becomes mandatory if the device is to be UKCA marked (and the manufacturer is based outside the UK).

5. Transition Timelines

Q: In your presentation, you indicate that the MDR and IVDR will not apply in GB as their Dates of Application are beyond the end of the transition, but on another slide, you indicate that GB will recognize EU CE marking under Directives and Regulations until 30 June 2023, so will an MDR compliant device be able to be placed on the UK market on 1 January 2021, assuming it has been registered with MHRA?

The MDR and IVDR will not apply in the UK; however, the CE mark and CE certificates issued by EU NBs under the Directives or Regulations will be accepted in the UK until June 2023. There is an unresolved question on the status of devices and other provisions such as SSCPs, PSURs, implant cards, and Article 117 that are included in the scope of the MDR and IVDR but not in the Directives. More guidance is expected in this area from the Government.

Q: If the manufacturer introduces a new product under the EU MDR after 1 January 2021 and before 1 January 2023, 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 January 2023, but only until June 2023.

Q: 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.

Q: 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 medical devices will have until 30 June 2023, when UKCA marking becomes mandatory.

Q: From 30 June 2023, do you think it will be mandatory to recall medical devices still placed on the GB market with an EU MDD certificate?

No new devices can be placed on the GB market from 1 July 2023 without the UKCA mark.

Q: If we want to apply the UKCA mark on Class 1 now while doing packaging change, can we? Do we need a new DoC?

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

Q: I have a client who received push back for labelling their product with both CE and UKCA marks after they had properly registered with the MHRA per the requirements. Is this because the UKCA mark can only be applied AFTER 1 January 2021?
CE marked devices will be accepted in the UK until 30 June 2023. 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 UK Approved Body.

Q: 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 become UK Approved Bodies. UK ABs 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 requirements depending on the route to conformity followed.

Q: If the MDR and IVDR doesn't apply to GB, will GB still accept a product approved under the MDR until July 2023?
Yes, that is correct; GB will accept devices CE marked devices under IVDR/MDR until June 2023.

Q: "Established compliance with UK MDR 2002" does this mean we have to be assessed by BSI prior to using the UKCA mark?
Depending on the classification of the medical device, a UK Approved Body assessment will be required before a UKCA certificate can be issued based on which the device can be UKCA marked.

Q: 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?
GB will continue to operate under the Directives in the short term. However, a new legislative framework will be introduced via the MMD Act of 2021. It is unknown whether and how much this new legislative framework will align with IVDR/MDR.

Q: If we transfer an EC Certificate 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 EC Certificates.

Q: Is it possible to ask for UKCA certification just before the MDR CE certification 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 BSI Scheme Manager.

6. MHRA Registrations

Q: How do we register now in the grace period with the MHRA?
Information on registering medical devices is available on the below webpage:https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

Q: A currently certified medical device under BSI NL, which is marketed in the UK, should have on the labelling the UKRP?
In the case of medical devices 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.

Q: 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 2023. 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.

Q: If we have a CE mark issued by another non-BSI EU NB, can we supply the device to the UK until June 2023?
Yes, however, devices will need to be registered with the MHRA as per the timelines defined on the below webpage: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#registrations-in-great-britain.

Q: 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 the below webpage:https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market
For medical devices that are already registered with the MHRA, manufacturers are required to re-confirm the device details.

Q: Are registrations per GMDN code?
Information on registering devices is available on the below webpage:https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

7. UKRP

Q: If a company has multiple distributors in the UK, will each be required to list as a UK Responsible Person, or just one?
Only one UKRP is required.

Q: 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 medical devices is available on the below webpage:
https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices
It is anticipated that further guidance will be published on the registration of devices.

Q: Can the UKRP be an organization, or does it need to be an individual?
It can be an organization similar to the EU Rep.

Q: Is a letter of delegation required for the UK Responsible Person? Or is an agreement required as per EU AR requirements?
The requirements are expected to be similar to those that apply for EU Reps.

Q: 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 Declaration of Conformity, and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA.

Q: I have a question: Will the UK RP 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.

Q: Are there any qualifications needed to be a UK Responsible Person?
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.

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

Q: If medical devices 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.

Q Does the UK MDR 2002 require the UKRP to verify the Technical Documentation and Declaration of Conformity of the Legal Manufacturers?
Please refer to the MHRA website for responsibilities of the UKRP (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#responsible)

Q: For placing a product on the EU market, if we are a UK manufacturer, do we have to appoint an EU Responsible Person who will be based in the EU?
Yes, as the UK is no longer in the EU, manufacturers outside the EU require an EU Rep based in either the EU or Northern Ireland.

Q: You mentioned UKRP information needs to be included in the labelling. Does that 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 a UKRP on either labels or IFU.

Q: What are the legal responsibilities and liabilities of the UKRP?
Information on responsibilities of the UKRP is available on the below webpage:
https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#responsible

Q: Is there a grace period for registering a UKRP? In the MHRA webinar, they stated the UKRP must be in place by the time of device registration.
Information on this is available on the below webpage:
https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#responsible

Q: On slide six, it is mentioned that only one UKRP is allowed per legal manufacturer. Can you confirm this is per article/device? I understood that a legal manufacturer that, e.g. has different product lines could use several UKRPs. Link to the legal text.
This is based on feedback BSI received from the MHRA that a manufacturer should appoint only one UKRP for all their devices.

Q: Has an agreed symbol been defined to represent the UKRP?
No agreed symbol.

Q: 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.

Q: I would like to ask about the UKRP; our company is based in the UK but have a part of the manufacturing facility in the US. The person who is responsible for regulatory aspects is based in the US; do we still have to identify the UKRP, which will be based in the UK?
A UKRP must be based in the UK.

Q: When the product is labelled with a CE and UKCA mark, both ECREP and UKREP should also be labelled?
Yes.

8. Associated EU Directives

Q: 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.

Q: What are the arrangements/ plans for UKCA marking for the replacements for EU Directives (EMC, RoHS3, Low Voltage, for example) 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.

Q: 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.

Q: Alongside the MDD/MDR, we have compliance to the EU radio equipment directive, too (wireless hearing aids). I understand we need to comply with UK Radio regulations by January 2022. Will we need to affix a UKCA mark to products for this before we have applied for the UK MDR compliance (before January 2023)?
Recent guidance indicates that the longer of the two deadlines will apply.

Q: Some medical devices, which will also be applied for Radio directive, in that case, MDR2002 is prior to it?
Recent guidance indicates that the longer of the two deadlines will apply.

9. EU/GB/NI

Q: Will UK NBs still offer the CE mark route under MDR post 1 January 2021?
No. UK NBs will become UK Approved Bodies and will be able to conduct conformity assessment for the UK legislation. As an exception, UK ABs, which are designated to MDR/IVDR, can also conduct conformity assessments against the MDR/IVDR for the Northern Ireland 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 Northern Ireland.

Q: What would be better for a small R&D company – go straight for CE marking, or attempt to comply with both CE marking and UKCE requirements?
Depends on your most important market, an EU CE will cover both until 30 May 2023.

Q: Back to the MDR. 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? Can you elaborate a bit more, please?
Devices CE marked via self-certification, whether under the Directives or Regulations, will be accepted in the UK until June 2023.

Q: 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 30 June 2023.
In order to apply the UKCA mark, devices need to undergo a UKCA conformity assessment process.

Q: 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 Approved/Notified Bodies?
UK Approved Bodies cannot conduct conformity assessment for EU CE requirements. Only EU NBs can conduct conformity assessments against the EU requirements. BSI already operates as an EU NB (BSI NL 2797), and BSI also operates as a UK Approved Body (BSI UK 0086) from 1 January 2021.

Q: Is the Republic of Ireland under the UK MDD 2002 or under the EU MDR?
The Republic of Ireland is part of the EU, so CE marking requirements will be applicable.

Q: Add NI marking makes EU reject it? But NI will accept without NI marking? Does that make the NI marking redundant?
Information related to placing devices on the NI market is available on the below webpage:
https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#NI
Devices bearing the UK(NI) mark cannot be further circulated into Europe after being placed in the NI market.

Q: I have two questions: for the NI mark, can you explain if we also will have an NI audit or the CE mark is OK for the NI mark? How does it work for the NI mark?
Information on placing devices on the market to NI is available on the below webpage:
https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#NI
CE marking is valid in NI if the assessment is carried out by an EU NB.

Q: Please advise on the Technical Documentation since the EU MDR will need to comply with GSPR; however, UK MDR 2002 need to comply with essential requirements?
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.

Q: Thank you for a clear and very informative presentation. My question is: how do we handle, e.g. grace periods and other issues that will appear with medical devices that are classified differently according to the MDR and the MDD that will apply in GB?
For GB, follow the classification of devices as per the UK legislation UK MDR 2002, which is based on the Directives.

Q: When one has achieved an EU MDR CE Mark and UKCA mark, will reporting significant changes be streamlined to both conformity assessment bodies?
BSI has streamlined its processes. In such cases, one change notification form can be submitted towards both the legislations.

Q: Does the EU MDR Technical Documentation meet the UKCA requirements, or is a separate/specific UK Technical Documentation required for the UKCA?
In general, the MDR requirements 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 requirements clearly against the applicable legislation.

Q: Also, for Technical Documentation under UKCA assessment, can we use our EU Technical documentation and integrate UKCA specific requirements for both?
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.

Q: If we put a UKCA and CE mark on the device together, do we need to be audited by the same Notified Body?
Not necessarily. A manufacturer can choose to work with a different EU NB and a UK AB. 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.

Q: We have a 2797 CE Cert and are planning to apply for UKCA (0086) Approval. Will unannounced audits be conducted at 2797 and UKCA (0086) respectively after receiving both Certs?
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.

Q: Are UK manufacturers able to self-declare a Class I device with a CE mark?
If the device has a CE mark, it can be placed on the GB market until 30 June 2023. Alternatively, manufacturer can self-declare the class I device under the UK legislation directly and apply the UKCA mark once requirements have been met.

Q: Will CERs written to the MDR be acceptable for UKCA?
It is plausible. However, it is up to the manufacturer to show that the requirements of both the legislations have been met.

Q: If I am seeking to market a new device in the UK without any prior certifications (for company or device), am I required to pursue the UKCA pathway? Or can I pursue the CE mark and market in the UK until 2023?
The latter approach is possible.

Q: In our QMS, can we maintain references to the MDD, or will we need to update by 2023 to reference the UK regulations?
QMS should refer to the UK legislation when the manufacturer establishes compliance to the UK legislations.

Q: If the CE mark is accepted even after June 2023 in the UK, why would a manufacturer need both a UKCA mark and CE mark on their product?
CE marking will only be accepted in NI beyond June 2023. UKCA marking becomes mandatory in GB from 1 July 2023.

Q: 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.

10. Risk Class Queries

Q: For Class I medical devices, will the UKCA mark be recognized on the EU Worldwide pack with a CE mark after June 2023? 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.

Q: Following the recent announcement of the UKCA mark, I have a question related to devices accessories. We are a legal manufacturer of Class IIa medical devices based in the UK. Our Notified Body is BSI, and it has transitioned to BSI The Netherlands (CE 2797). Our understanding is that we can continue to place our devices on the UK market until 30 June 2023 before having to comply with UKCA labelling requirements. What is not clear is how this requirement translates to our device accessories.
Accessories to medical devices are treated as medical devices themselves. So, the same rules apply to accessories as well.

Q: Is there any guidance on competent authority approval requirements for combination devices under MDD Annex I point 7.4 for UKCA cert devices?
The requirements would be expected to mirror those of the current consultation requirements under the MDD.

Q: If you have a product that must meet the MDR by May 2021 due to its classification (e.g. Class III custom-made) to continue to sell in the EU, but you only sell the product in the UK, will you require an MDR certificate, or can you remain with an MDD certificate to have a UKCA mark based on meeting the requirements of the MDD?
If the intention is to just sell in GB, then the manufacturer has the option to just consider the UKCA requirements. However, please note that NI will continue to operate under EU rules, and hence MDR will apply in NI from 26 May 2021.

Q: What about certification for Class I devices; can a manufacturer self-certify these products, and is a UKCA certification (FQA) needed?
Manufacturers of Class I medical devices 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 medical devices that are sterile or have a measuring function require approval from the UK Approved Body in order to be affixed with the UKCA mark and placed on the Great Britain market.
Please refer to the below webpage: (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain).

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

Refer to MHRA guidance on registrations (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market).

Q: Hello, do you have information on whether an Article similar to the EU MDR Article 117 is in preparation?
No equivalent under the UK MDR 2002. It may be included in the future legislative framework for the UK.

Q: For Class I medical devices, when/how should we apply UKCA?
Such medical devices can be self-certified against the UK MDR 2002 legislation.

Q: Can a manufacturer of self-declared / General IVDs place the UKCA on the products from now into the future?
Yes, as long as compliance has been established with the UK MDR 2002 as amended by EU exit legislation.

Q: Do all devices need to undergo conformity assessment prior to July 2023? Is there any grandfathering?
It is unknown at this time.

Q: Going back to custom made devices, in the case of 'customized procedure packs', will each integration need to be registered individually?
Refer to MHRA guidance on registrations (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market).

Q: Do you have any insight into whether drug-device consultations between the MHRA and a European Notified Body will continue to be valid for devices already bearing the CE mark before January 2021?
The UK Approved Body 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.

11. BSI Procedures

Q: With regard to BSI being the only UK AB with full scope – what about TUV Sud, albeit a German company, but with a UK base?
Currently, only the UK-based NBs have automatically been designated as UK Approved Bodies. Other European Notified Bodies will have to undertake a due designation process with the MHRA and accreditation process with UKAS before they can be designated as a UK Approved Body.

Q: 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.

Q: 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.

Q: In scenario three, would the UKAB on the labelling be 0086?
The UKABs retained their EU identification number (0086 for BSI UK).

Q: So, to meet the UKCA mark, will BSI follow the same process under the IVD Directive, 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 below webpage: https://www.legislation.gov.uk/uksi/2002/618/contents/made

Q: Can our BSI NL account manager liaise with BSI UK to organize our UK audit?
Yes, they will be able to support you.

Q: Does BSI UK consider conformity assessments by other NBs than BSI NL?
Yes. BSI will apply an abridged conformity assessment process that is very similar to the Transfer process.

Q: 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, I expect the manufacturer can combine documentation too.
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.

Q: For scenario five, 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 will issue certificates for the European legislations. Separate stand-alone certificates will be issued by BSI UK for the UK MDR 2002 legislation.

Q: If we transfer a CE mark certificate to a UKCA mark, 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.

Q: For an initial application for both UKCA and EU 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 the legislations.

Q: Will BSI provide a "gap" assessment comparing the UK MDR 2002 and the EU MDR?
BSI, in its role as a Notified Body or UK Approved Body, cannot provide any form of gap assessments.

Q: Have the UK Approved Bodies started assessing the Technical Documentation and issuing UKCA certificates?
Yes.

Q: 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.

Q: 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.

12. QMS / ISO 13485 / MDSAP

Q: 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 the end of June 2023. If the question is referring to ISO 13485 certificates as Quality certificates, then these are not mandatory for accessing the GB market.

Q: 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.

13. IVD Specifics

Q: 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 medical device on 1 January 2021 and no later?
Such medical devices should have already been registered with the MHRA as per the current requirements.

Q: Currently, COVID-19 test devices, and their accessories, for self-test 'home use' must go through the MHRA by derogation rather than NB. Will BSI be in a position, as UK Approved Body, 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.

Q: 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 30 May 2023?
Self-certified IVD devices will continue to be self-certified in GB under the IVDD immediately after 1 January 2021. How long they can remain self-certified will depend on the requirements of the secondary legislation that is expected to introduce a new regulatory framework in the UK.

Q: 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 MDR 2002 and place the UKCA mark after 1 January 2021. Is it expected that this "General IVDs" class 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.

Q: From slide 6 – do the registrations also apply to IVDs or medical devices only?
Please refer to the MHRA website for the list of IVDs to be registered and related timelines (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#registrations-in-great-britain)

Q: Does the recognition of the EU CE mark also include IVDs or only medical devices?
CE marked devices will be accepted on the Great Britain market until 30 June 2023. This applies to IVD and medical devices 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)

Q: Can both CE and UKCA markings appear on the same IVD?
Yes, if the device complies with both the legislations.

14. Future Plans

Q: Could you take your crystal ball and try to see how changes would 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 UKA with BSI?
BSI will try to combine assessments for all applicable legislations where possible.

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