



British Dental Industry Association

Frequently Asked Questions:

MHRA Proposals for International Recognition of Medical Devices

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Disclaimer:

This document has been prepared by the BDIA according to the Association's best understanding of currently available information and clarifications received from Government, the MHRA, conformity assessment bodies and other sources.

The information contained in this document is not final and should be considered as being subject to change. It is not published or endorsed by the MHRA, is not an official document and is meant for guidance only. Companies should consider whether they need separate professional advice before making specific preparations.

This document will be updated as new information is received and revisions noted in the change log. This FAQ is intended to be read in conjunction with the MHRA's published [Statement of Policy Intent](#).

Frequently Asked Questions

Q1. What is a Statement of Policy Intent?

A1. The MHRA's announcement does not reflect current legislation, draft legislation or official Government policy. The statement "describes the draft policy for recognition by the UK of international regulators' approvals of medical devices", providing detail of the intent and rationale without impacting existing regulatory requirements or guidance.

Q2. Does the proposal include plans for recognition of UKCA in other markets?

A2. The Statement of Policy Intent does not include proposals for the recognition of UKCA certification in other markets. The MHRA has previously advised us that, while they are hopeful that recognition of UKCA in other territories can be achieved in future, this would be dependent on trade agreements with the involvement of the Department for Business and Trade (DBT).

Q3. Will I need an Approved Body?

A3. Some of the routes reference the need for some element of review, such as of PMS plans, or of an "abridged assessment".

The detail of how these assessments will be carried out, and who will undertake them, has not been published and remains the focus of ongoing MHRA planning.

Based on the information made available in the MHRA's Statement of Policy intent, the majority of eligible products would not require an assessment prior to placing on the market.

Q4. Will I have to apply the UKCA mark?

A4. No. None of the proposed routes include a requirement to place the UKCA mark on labelling. This is because the proposed routes would not lead to the issuance of UKCA certification or a UKCA mark, but would instead grant a "certificate of international recognition" that would grant access to the Great Britain market.

Q5. Does this mean the UKCA mark is being discontinued?

A5. No. The UKCA mark and the underlying regulatory framework will continue to exist, and manufacturers will be able to self-certify to UKCA as well as apply for UKCA certification through a UK Approved Body.

The underlying regulatory framework of UKCA will also serve as a reference for the international recognition process.

Q6. Are all types of device eligible?

A6. No. The following products would be excluded from international recognition:

- exempted in-house devices
- custom-made devices
- Software as a Medical Device (SaMD) (including Artificial Intelligence as a Medical Device (AIaMD)) products that do not satisfy our [intended purpose guidelines](#)
- SaMD (including AIaMD) products approved via a route which relies on equivalence to a predicate (US 510(k))
- products granted market access in the CRC via a recognition route
- Class IIb (non-well established technology (WET)) implantable and III medical devices approved via a route which relies on equivalence to a predicate (US 510(k))
- companion diagnostics approved via a route which relies on equivalence to a predicate (US 510(k))
- companion diagnostics and combination products containing medicinal substances that are not licensed in the UK
- products excluded from the scope of UK MDR 2002, listed in [Regulation 3](#)

Q7. Will I have to change labelling?

A7. The Statement of Policy intent does not include any requirements that would necessitate direct changes to the product label. Labelling requirements noted in the statement include:

- The product must have English language labelling and packaging
- Compliance with GB requirements for labelling materials of concern (e.g. for substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, or could result in sensitisation or an allergic reaction).
- Inclusion of UK Responsible Person details. However, this may be via over-labelling, and the MHRA is investigating options for digital labelling or digital label solutions.*
- The product must have a physical unique device identified (UDI) on parts and labels in compliance with the requirements of the UK MDR or the CRC.

*see also Q8 below.

Q8. Will I still need a UK Responsible Person?

A8. Yes. To place a device on the Great Britain market – including via the proposed international recognition routes – manufacturers based outside the UK are required to appoint a UK Responsible Person.

It should be noted that, at present, existing requirements for the UKRP allow for their details to be included on the product labelling or the outer packaging, or the instructions for use in cases where the UKCA mark has been affixed. This differs from the requirements for the international recognition proposals laid out in the Statement of Policy intent, which do not refer to the option to include UKRP details in the instructions for use. Clarification is required from MHRA as to whether this is an intended divergence, or whether manufacturers utilising international recognition will be able to place UKRP details in the instructions for use.

Q9. How will the assessments work and who will carry them out?

A9. The MHRA has not published details of how any assessments will be carried out, or the organisations conducting them. It is possible that such assessments (and responsibilities for post-market oversight) will fall to UK Approved Bodies, that the MHRA will carry out this work itself, or a combination of the two.

Q10. When will the policy apply from?

A10. No firm timeline has been provided for the introduction of international recognition. However, the policy is expected to be introduced as part of the future core regulations which, according to the MHRA's "[Roadmap towards the future regulatory framework for medical devices](#)" is expected to be shared in draft form in late 2024, before being laid in Parliament and entering into force in 2025. The timings given in the roadmap are estimates only, and we have already seen some delays to other milestones, for example the delay of the Statutory Instrument on PMS due to the General Election.

Q11. How are the proposals affected by the General Election?

A11. Any statement about future policy should be viewed with some caution in light of an upcoming election. While a change of government could result in the policy either not being pursued or in it being substantially altered, we have not been made aware of any specific reasons to believe that this would be the case.

A more likely impact of the General Election on the introduction of international recognition would be in the form of a delay, with the Parliamentary timetable having been severely impacted.

Q12. What about other markets/regulators?

A12. The only regulators/markets identified in the Statement of Policy intent are the EU, USA, Canada and Australia. However, MHRA has previously indicated an interest in expanding to other regulators such as Japan and Singapore.

Q13. What about the Medical Device Single Audit Programme (MDSAP)?

A13. As the MHRA is not a full member of MDSAP, an MDSAP audit/certification would not be sufficient for direct market access in Great Britain. However, two of the CRCs included in the Statement of Policy Intent (Canada and the USA) are MDSAP members and so the audit process would be relevant for obtaining certification in those markets.

The MHRA is currently an Official Observer of MDSAP, and any future progression to full member status could change this situation.

Q14. Does this affect existing CE recognition arrangements?

A14. No. Existing MHRA arrangements for the [recognition of CE marked devices](#) will continue to apply.

Q15. I am already placing products on the GB market under CE certification, will I need to do anything else?

A15. No. Devices that are being placed on the market under existing arrangements for the [recognition of CE marked devices](#) are unaffected.

Q16. My device has been placed on the market in the EU/USA/Canada/Australia under a recognition route from another regulator, will I be able to use the international recognition route for Great Britain?

A16. No. Devices that have been granted access in a CRC via a recognition route are excluded from international recognition.

Q17. What happens if the classification of my device differs between the MHRA and CRC?

A17. In cases where the classification of the device differs in the CRC to that under the UK MDR 2002, Route 4 (Reliance with abridged assessment and device-specific requirements) will apply. This would be the cases wherever a difference of classification exists, regardless of the classification. In theory this could apply even where the classification under the UK MDR 2002 is lower than in the CRC, although the MHRA has not specifically clarified how such cases would be handled.

Q18. How long will the certificate be valid for?

A18. The certificate of international recognition providing Great Britain market access would be in accordance with the validity of the supplied certificate from the CRC. If the CRC certificate expires, recertification would be required.

Q19. What happens if the validity of the CRC certificate is removed?

A19. If the CRC certificate is no longer valid, e.g. if an EU Notified Body has withdrawn the certificate, the certificate of international recognition would also no longer be valid.

Q20. What should companies do now to prepare or communicate to suppliers?

A20. We would encourage BDIA members to familiarise themselves with the proposals and communicate them to their suppliers. This should be done with the understanding that publication of the Statement of Policy Intent has not changed any current requirements of medical device regulation in Great Britain, nor is it a binding commitment for the Government to introduce the proposed changes in future.

Any actions to be taken on the basis of the statement are a matter of individual commercial decisions. Manufacturers considering certification to UKCA or one of the frameworks covered by the proposals should understand that there is a high likelihood of significant changes to the available routes to the Great Britain market in the short to medium term, and that greater certainty regarding the introduction of such policies and their detailed requirements is expected in the coming months.

Q21. Will the proposals apply in Northern Ireland?

A21. While the MHRA is the Competent Authority for Northern Ireland, the proposed international recognition framework would only apply to Great Britain. Northern Ireland remains subject to the EU Medical Device Regulation. Further, 'Qualifying Northern Ireland Goods' can continue to be placed on the Great Britain market with valid CE certification on an indefinite basis independently of these proposals.

Q22. If an Approved Body is required, either for an abridged assessment or for post-market requirements, will they recognise work carried out by another organisation, e.g. a different EU Notified Body?

A22. As the details of the assessments, who the organisations that would be carrying them out, have yet to be confirmed this is not known at this time. Conformity assessment bodies have previously expressed their concern regarding reliance on work carried out by another organisation when assessing a product. UK Approved Bodies have, in conversations with the BDIA and in presentations to BDIA members, indicated that work carried out by a partner organisation (e.g. BSI UK and BSI Netherlands) could be relied upon as part of an 'abridged assessment' but that devices certified by an entirely separate organisation would require a more comprehensive review. However, this has not been confirmed by MHRA and remains one of the areas subject to further review.

Q23. Will products already certified to UKCA require a new assessment when the new regulations are introduced?

A23. The Statement of Policy intent reiterates the MHRA's intention, set out in the Government's [response to the 2021 consultation on future medical device regulation](#), to "introduce transitional arrangements for UKCA marked devices with the future core regulations". This would indicate that devices that have already been UKCA marked according to the current requirements could have the validity limited when the new requirements are introduced, with the potential for an additional assessment being required.

Q24. Without label or product marking, how will a user/buyer know that a product is compliant?

A24. The proposed routes, leading to the issue of a "certificate of international recognition", do not include product marking or labelling requirements (apart from UKRP and UDI information – see Q7). Based on the information currently available it may, therefore, not be possible to determine whether a product is in compliance with the requirements of the international recognition routes based on physical examination. However, the MHRA is increasing its post-market oversight and all products,

regardless of the route to market they have followed, will need to have been registered with the MHRA prior to placing on the market.