Medicines & Healthcare products Regulatory Agency

Medical Devices Regulations: Routes to market and in vitro diagnostic devices

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for ensuring that medical devices are safe and effective for use by patients.

Medical devices are products or equipment that are used for medical purposes, such as diagnosis, prevention, monitoring or treatment of diseases or injuries. They include a wide range of products, such as pacemakers, artificial hips, blood glucose meters, pregnancy tests, medical decision support software, syringes, surgical instruments and wheelchairs.

At the MHRA, we put patients first in everything we do, right across the lifecycle of the products we regulate, and we ensure that medicines and healthcare products available in the UK are safe and effective. We want to develop a future regime for medical devices that enables:

- improved patient and public safety;
- innovation;
- close alignment with international best practice; and
- risk proportionate regulation of medical devices.

Medical devices and in vitro diagnostic (IVD) devices in Great Britain (England, Wales, and Scotland) are regulated under the Medical Devices Regulations 2002.

We are seeking views on proposals to update four areas of the future regulatory framework for medical devices:

1. International reliance
2. UKCA marking
3. In vitro diagnostic devices
4. Assimilated EU law

The MHRA is inviting members of the public – including patients, medical device researchers, developers, manufacturers and suppliers, clinicians and other healthcare professionals – to provide their views on proposed changes to the regulatory framework for medical devices that will help us meet our objectives.

This consultation applies to medical devices in Great Britain. For guidance on the regulation of devices in Northern Ireland, see Regulation of devices in Northern Ireland.

Please read the consultation document prior to completing the consultation survey. You may benefit from having this available when answering the questions.

You do not need to complete the questions in one go, click the same link and you will be able to come back to it at another time to finish it off. Please note that only fully submitted responses will be analysed.

The deadline to complete this consultation is Sunday 5 January 2025.

If you have any questions please contact futuredevicesregulations@mhra.gov.uk.

International Reliance

1. Do you agree with all elements of the MHRA's proposed international reliance routes?

- ○ Yes
- ○ No
- ○ No opinion

2. Would you like to see the proposed Route 1 introduced?

- ○ Yes
- ○ No
- ○ No Opinion

Please provide any further comments you may have on Route 1 (optional)

3. Would you like to see the proposed Route 2 introduced?

- Yes
- No
- No opinion

Please provide any further comments you may have on Route 2 (optional)

4. Would you like to see the proposed Route 3 introduced?

- Yes
- No
- No opinion

Please provide any further comments you may have on Route 3 (optional)

5. Would you like to see the proposed Route 4 introduced?

- ◯ Yes
- ◯ No
- ◯ No opinion

Please provide any further comments you may have on Route 4 (optional)

6. Certain medical devices approved via 510(k) are excluded in the framework above: software as a medical device, implantable Class IIb devices (other than non-resorbable sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors), and Class III medical devices. Would you like to see these devices added into the scope of Route 4 if their rationale for equivalence to a “reference device” meets the (new) UK MDR requirements for entire equivalence on a biological, technical and clinical basis? Please note that these requirements are summarised in Annex C to support this decision.

- ◯ Yes
- ◯ No
- ◯ No opinion

Please provide any further comments you may have for your answer (optional)

UKCA Marking

7. Do you support the proposal to remove the UKCA marking requirement for devices which undergo the UK conformity assessment process?

- ○ Yes
- ○ No
- ○ No opinion

Please provide any further comments you may have for your answer (optional)

8. Do you support the proposal to remove the UKCA marking requirement for medical device labelling (e.g. packaging and instructions for use) for devices which undergo the UK conformity assessment process?

- ○ Yes
- ○ No
- ○ No opinion

Please provide any further comments you may have for your answer (optional)

In Vitro Diagnostic Devices

9. Do you support the proposed conformity assessment processes for IVD devices (including Software IVDs) in Great Britain?

- ○ Yes
- ○ No
- ○ No opinion

Please provide any further comments you may have for your answer (optional)

10. Do you think that UKCA declaration of conformity and QMS certification are adequate pre-market controls for Class B IVD devices?

- ○ Yes
- ○ No
- ○ No opinion

Please provide any further comments you may have for your answer (optional)

11. Do you support the requirement for ISO13485:2016 standard to be met for Class B IVD devices?

- ○ Yes
- ○ No
- ○ No opinion

Please provide any further comments you may have for your answer (optional)

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12. If the proposed approach is implemented, do you think that Class A and B IVD devices should be removed from the scope of international reliance?

- ○ Yes
- ○ No
- ○ No opinion

Please provide any further comments you may have for your answer (optional)

Assimilated EU Law

13. Do you agree with the MHRA's proposal to remove the revocation date of the four specified pieces of assimilated EU law?

- ○ Yes
- ○ No
- ○ No opinion

Please provide any further comments you may have for your answer (optional)

About you

1. In which capacity are you primarily responding to this survey?

- ○ An individual sharing my personal views and experiences
- ○ An individual sharing my professional views
- ○ On behalf of an organisation

2. Are you currently working as a clinical professional? Which of the below describes you best?

- ○ No, I'm not a clinical professional
- ○ Yes, I'm a clinical professional
- ○ Other

What is your clinical profession?

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3. Which of the below describes your organisation best?

- ○ Trade Association
- ○ Business
- ○ Patient group
- ○ Professional representative group
- ○ Professional regulator
- ○ Research organisation
- ○ Other

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4. Which parts of the UK and other global markets do you currently supply?

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5. Where do you live in the UK?

- ○ England
- ○ Northern Ireland
- ○ Scotland
- ○ Wales
- ○ I live outside the UK

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6. Where does your organisation operate? (Please tick all that apply)

- ☐ England
- ☐ Wales
- ☐ Scotland
- ☐ Northern Ireland
- ☐ Outside the UK

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7. What is your ethnic group?

- [ ] Any other Asian background
- [ ] Any other Black/African/ Caribbean background
- [ ] Any other ethnic group
- [ ] Any other mixed ethnic background
- [ ] Asian/Asian British – Bangladeshi
- [ ] Asian/Asian British – Chinese
- [ ] Asian/Asian British – Indian
- [ ] Asian/Asian British – Pakistani
- [ ] Black/African/Caribbean /Black British – African
- [ ] Black/African/Caribbean /Black British – Caribbean
- [ ] Mixed ethnic group – White and Asian
- [ ] Mixed ethnic group - White and Black African
- [ ] Mixed ethnic group – White and Black Caribbean
- [ ] Not Known
- [ ] Other ethnic group – Arab
- [ ] White – Any other White background
- [ ] White – English/Welsh/Scottish/ Northern Irish/British
- [ ] White – Gypsy or Irish Traveller
- [ ] White - Irish
- [ ] Prefer not to say

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8. How many employees does your business employ? An employee is anyone aged 16 years or over that an organisation directly pays from its payroll(s), in return for carrying out a full-time or part-time job or being on a training scheme. It excludes voluntary workers, self-employed and working owners who are not paid via PAYE.

- ( ) 0-9
- ( ) 10-49
- ( ) 50-249
- ( ) 250-499
- ( ) 500+
- ( ) Don't know

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9. Does your business produce or supply any of the following products? (Please tick all that apply)

- [ ] Medicines
- [ ] Medical Devices
- [ ] In Vitro Diagnostic Medical Devices
- [ ] Borderline Substances (e.g. medical nutrition)
- [ ] None of the above [exclusive]
- [ ] Don't know [exclusive]

10. Does your business produce or supply any of the devices affected by common specification measures? (Please tick all that apply)

- [ ] COVID-19 tests
- [ ] Other
- [ ] Don't know

Satisfaction Survey

1. It was easy to participate in this opportunity (optional)

- ○ Strongly agree
- ○ Agree
- ○ Neither agree or disagree
- ○ Disagree
- ○ Strongly disagree

2. The supporting information was understandable (optional)

- ○ Strongly agree
- ○ Agree
- ○ Neither agree or disagree
- ○ Disagree
- ○ Strongly disagree

3. What could we do better? (optional)

Thank you for your time in completing this consultation.

If you have any questions please contact futuredevicesregulations@mhra.gov.uk.

This survey is now closed.