Medicines & Healthcare products Regulatory Agency

Public consultation on Common Specification Requirements for In Vitro Diagnostic Devices

The in vitro diagnostic medical device (IVD device) industry is a vital part of the UK's healthcare system. IVD devices play a key role by contributing to accurate and timely medical decisions.

IVD devices in Great Britain (England, Wales, and Scotland) are currently regulated by the Medicines and Medical Devices Act 2021 and the Medical Devices Regulations 2002.

We are seeking views on the inclusion of common specification requirements in the Medical Device Regulations 2002 before certain high risk IVD devices can receive UKCA marking and be placed on the Great Britain market, and to remove the Coronavirus (COVID-19) Test Device Approval requirements for COVID-19 test devices from the Medical Device Regulations 2002. Common Specification requirements will improve the safety profile and the quality of high risk IVD devices, including COVID-19 test devices. This policy would require manufacturers of certain high-risk IVD devices to demonstrate that their device complies with the Common Specification requirements to protect public health and avoid duplication of regulatory requirements for COVID-19 tests.

The MHRA is inviting members of the public, including the views of patients, medical device researchers, developers, manufacturers and suppliers, clinicians, other healthcare professionals to provide their views on the introduction of common specification requirements to the regulatory framework for IVD devices in Great Britain.

Under the terms of the Windsor Framework, Northern Ireland continues to follow EU regulations for IVD devices, the IVDR. On 21 March 2024, The Medical Devices In Vitro Diagnostic Devices etc. Amendment Regulations 2024 came into force and introduced provisions required for implementing the IVDR 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 Friday, 14th June 2024.

Common Specifications Policy Proposal

1. The Government proposes that the Medical Devices Regulations 2002 incorporates the Common Specifications for certain Class D IVDs, as set out in the Commission Implementing Regulation (EU) 2022/1107. Do you agree with this proposal?

- ○ Yes
- ○ No
- ○ No opinion

2. Do you think meeting Common Specifications requirements should be a requirement in a Post Market Performance Follow-up Plan?

- ○ Yes
- ○ No
- ○ No opinion

3. The Government proposes to remove the requirements for Coronavirus test devices, from the Medical Devices Regulations 2002. The Government proposes to require COVID-19 test devices to undergo a conformity assessment by an Approved Body, meeting Common Specifications requirements in line with Commission Implementing Regulation (EU) 2022/1107, the EU Common Specifications for certain Class D IVDs. Do you agree with this proposal?

- ○ Yes
- ○ No
- ○ No opinion

About you

4. 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

5. Are you currently working as a clinical professional?

- ○ Yes
- ○ No
- ○ Other

6. What is your clinical profession?

7. Where do you live in the UK?

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

8. Which of the below describes your organisation best?

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

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

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

10. 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

11. Does your business produce or supply any of the following products?

- ☐ Medicines
- ☐ Medical devices
- ☐ In vitro diagnostic Medical Devices
- ☐ Borderline substances (e.g. medical nutrition)
- ☐ None of the above [exclusive]
- ☐ Don't know [exclusive]

12. Does your business produce or supply any of the devices affected by common specification measures?

- ☐ COVID-19 tests
- ☐ Other
- ☐ Don’t know

Satisfaction Survey

If you do not wish to leave your feedback, please select the 'Submit' button.

13. It was easy to participate in this opportunity

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

14. The supporting information was understandable

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

15. What could we do better?

Thank you for your time in completing this consultation. If you have any questions please contact futuredevicesregulations@mhra.gov.uk.