Medicines & Healthcare products
Regulatory Agency

Government response to the consultation on the Common Specification Requirements for In vitro Diagnostic Devices

Published 11 July 2025

© Crown copyright 2025

Open Government Licence

Produced by the Medicines and Healthcare products Regulatory Agency. www.gov.uk/mhra

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit http://www.nationalarchives.gov.uk/doc/open-government-licence or email: psi@nationalarchives.gsi.gov.uk.

Where we have identified any third-party copyright material you will need to obtain permission from the copyright holders concerned.

The names, images and logos identifying the Medicines and Healthcare products Regulatory Agency are proprietary marks. All the Agency's logos are registered trademarks and cannot be used without the Agency's explicit permission.

Contents

Contents 3
Ministerial foreword 4
Executive Summary 5
Introduction 6
    The respondents 7
Common Specifications 9
    Proposal 9
    Feedback 9
    The government response 11
Coronavirus Test Device Approvals 13
    Proposal 13
    Feedback 13
    The government response 14
Next steps 15

Ministerial foreword

The consultation on Common Specification requirements is a crucial step in ensuring that our regulatory framework for high-risk in vitro diagnostic medical devices (IVD devices) remains robust, effective, and aligned with international standards.

The responses we received from a diverse range of stakeholders, including IVD device manufacturers, healthcare professionals, trade associations and patient groups, have provided invaluable insights into the needs and concerns of the industry. The overwhelming support for the incorporation of Common Specifications into our regulations is a testament to the collective commitment to enhancing the safety and quality of IVD devices in the UK.

We recognise the importance of providing clear guidance and support to stakeholders during the implementation and transition to a new regulatory framework. The Medicines and Healthcare products Regulatory Agency (MHRA) is dedicated to ensuring a smooth and effective transition, and we will continue to engage with stakeholders to address any challenges that may arise.

I would like to extend my gratitude to all those who participated in the consultation and contributed their views. Your feedback is essential in shaping policies that protect public health and support innovation in the healthcare sector. Together, we are building a regulatory environment that not only safeguards patient safety but also fosters the development of cutting-edge diagnostic technologies.

Baroness Merron

Parliamentary Under-Secretary of State for Patient Safety,
Women's Health and Mental Health

Executive Summary

This document analyses the responses to the public consultation on the proposed amendments to the Medical Devices Regulations 2002 regarding the Common Specifications requirements for certain high-risk in vitro diagnostic devices (IVD devices), including COVID-19 tests. The consultation ran from 20 May to 14 June 2024 and received 39 responses from various stakeholders, such as IVD device suppliers and producers, healthcare professionals, trade associations, individuals, and patient groups.

The majority of the respondents agreed with the government's proposals to incorporate the Common Specifications for certain high-risk IVD devices, to make them a requirement in a Post Market Performance Follow-up Plan, and to remove the Coronavirus Test Device Approvals (CTDA) process and replace it with Common Specifications requirements.

The main theme that emerged from the responses was the need for clarity and guidance on the implementation of and transition to the Common Specifications.

The Medicines and Healthcare products Regulatory Agency (MHRA) appreciates the feedback from the respondents and will take it into account when finalising the policy and drafting the resulting legislation. We will also provide further information and support to impacted stakeholders to ensure a smooth and effective transition to the new regulatory framework.

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

Introduction

The MHRA is responsible for ensuring that in vitro diagnostic devices (IVD devices) meet the appropriate standards of safety, quality, and performance, and that they are used safely and effectively by healthcare professionals and patients.

An IVD device is used to examine samples taken from the human body. Samples can include saliva, blood, tissue, and urine. They are used to diagnose and monitor health conditions, and can also be used as a prevention measure by screening for possible health conditions. Examples of IVD devices include pregnancy tests, pap smear tests for cervical cancer screening, blood glucose meters for monitoring diabetes, and HIV testing kits.

The 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. In 2022, the in vitro diagnostic technology sector generated £3.5bn in turnover and employed 11,199 people across 235 businesses[1].

IVD devices in Great Britain (England, Wales, and Scotland) are regulated by the Medical Devices Regulations 2002 (MDR 2002). Northern Ireland applies different regulations for medical devices - more information can be found here. These proposed policy changes will therefore not apply to devices in Northern Ireland. However, the Government has carefully considered the internal market considerations of our approach and that is reflected in the proposed way forward.

The MHRA is committed to ensuring that the regulatory framework for medical devices addresses the most serious patient safety concerns and facilitates access to much-needed devices. In 2021, the previous Government consulted on changes to the MDR 2002, to improve how medical devices and IVD devices are regulated in the UK. In future legislative changes, we intend to take forward the key findings from that consultation, including the classification of IVD devices, to ensure that regulation is proportionate while protecting patient safety.

Building on the 2021 consultation and to inform further policy decision-making, we launched another consultation on 21 May 2024 inviting views from stakeholders and the public on the following proposed amendments to the MDR 2002: the inclusion of Common Specification requirements for manufacturers of high-risk IVD devices, and the removal of current Coronavirus Test Device Approvals (CTDA) requirements.

The consultation closed on 14 June 2024, and received 39 responses from a range of respondents, such as IVD device manufacturers, healthcare professionals, trade associations,

[1] Bioscience and health technology sector statistics 2021 to 2022 - GOV.UK

and individuals. This report presents the analysis of the responses to the consultation, highlighting the main themes, issues, and suggestions that emerged from the feedback.

The respondents

The consultation received 39 responses, of which 18 were from organisations and 21 were from individuals.

The organisations that responded to the consultation represented a variety of sectors and interests, such as IVD device manufacturers, healthcare professionals, trade associations, academic institutions, public bodies, and patient groups. Table 1 below shows the breakdown of the types of organisations that responded to the consultation.

Table 1. Types of organisations and number of responses

Types of organisation	Number of responses	Percentage of total responses
Business	9	50%
Professional regulator	3	17%
Trade association	2	11%
NHS	1	6%
Research organisation	1	6%
Public sector research organisation	1	6%
Public health	1	6%

The majority of the organisations were based in England, followed by Scotland, Wales, and Northern Ireland. Some respondents were also based in other countries. Table 2 below shows the breakdown of the locations of the respondents.

Table 2. Location breakdown of organisations

Location of organisation	Percentage of responses*
England	94%
Scotland	72%
Wales	72%
Northern Ireland	67%
Outside UK	61%

* Organisations could be based in more than one location

The individuals that responded to the consultation were either sharing their personal views or their professional views as employees or consultants of IVD device-related organisations. Table 3 below shows the breakdown of the types of individuals that responded to the consultation.

Table 3. Type of individual view and number of responses

Type of individual	Number of responses	Percentage of total responses
Personal view	4	10%
Professional view	17	44%
Total	21	54%

The majority of the professional individuals were again based in England, followed by Scotland, Wales, and Northern Ireland. The majority of the individuals sharing personal views were based in England (75%), followed by Scotland (25%). Table 4 below shows the breakdown of the locations of the respondents.

Table 4. Location breakdown of individuals

Location	Percentage of professional individuals*	Percentage of personal individuals
England	82%	75%
Scotland	18%	25%
Wales	12%	0%
Northern Ireland	12%	0%
Outside UK	24%	0%

* Individuals could be based in more than one location

Common Specifications

Proposal

Common Specifications are a set of requirements for high-risk IVD devices that relate to - amongst other things - clinical evidence, performance evaluation, analytical and diagnostic sensitivity and specificity, reference materials and measurement traceability, and post-market surveillance. We recognise the benefits of Common Specifications for enhancing the safety and quality of certain high-risk IVD devices, and for avoiding divergence with the requirements that apply in Northern Ireland and the EU given many manufacturers operate across the UK and EU. The Common Specifications are set out in the Commission Implementing Regulation (EU) 2022/1107. Therefore, the government proposes to amend the MDR 2002 to incorporate the Common Specifications for certain Class D IVD devices, and to require manufacturers to meet those Common Specifications as a condition for placing their devices on the Great Britain market. Common Specifications will only apply to Class D IVD devices where there is a significant risk associated with the use of the device for public health and patient safety.

Feedback

The consultation invited views on whether the MDR 2002 should include Common Specifications for certain Class D IVD devices, as set out in the Commission Implementing Regulation (EU) 2022/1107. Of the 39 respondents:

- 92% agreed with the proposal
- 8% disagreed with the proposal

See table 5 for a full breakdown of respondents, which includes Class D IVD device suppliers, health professionals, and COVID-19 suppliers.

Respondents who disagreed with the policy proposal were also asked to provide a rationale. The following reasons were given:

- Common Specifications are only required for high-risk devices. Therefore, Common Specifications requirements for SARS-CoV-2 devices should be removed, as they are recommended for reclassification to a lower risk class due to the World Health Organization (WHO)'s declaration of SARS-CoV-2 no longer being a Public Health Emergency of International Concern.
- It was unclear how the adoption of minimum device performance requirements would align with the MHRA's policy intent for the acceptance of approval from Comparable Regulatory Countries (CRC) for Class D devices.

- It was suggested that the MHRA should focus on influencing domestic and international standards rather than introducing another layer of regulation.

Table 5. Question one breakdown by respondent

Respondent	Yes	No	No opinion	Total responses
Overall view	36 (92%)	3 (8%)	0 (0%)	39
Organisations	16 (89%)	2 (11%)	0 (0%)	18
Professionals	16 (94%)	1 (6%)	0 (0%)	17
Individuals	4 (100%)	0 (0%)	0 (0%)	4
IVD Suppliers	18 (90%)	2 (10%)	0 (0%)	20
Class D IVD Suppliers	11 (92%)	1 (8%)	0 (0%)	12
COVID-19 Suppliers	9 (82%)	2 (18%)	0 (0%)	11

The consultation also invited views on whether meeting Common Specifications requirements should be a requirement in a Post Market Performance Follow-up Plan (PMPF). Of the 39 respondents:

- 82% agreed with the proposal
- 14% disagreed with the proposal
- 5% had no opinion

Refer to table 6 for a full breakdown of respondents which includes Class D IVD device suppliers, health professionals, and COVID-19 suppliers.

Respondents who disagreed with the policy proposal were also asked to provide a rationale. The following reasons were given:

- It would be impractical to require ongoing compliance to Common Specifications, as it would involve substantial work by the manufacturer. Maintaining compliance to Common Specification requirements should be done before product launch and not as an ongoing requirement.
- Tying Common Specifications specifically to the PMPF was seen as creating unnecessary restrictions on manufacturers and approved bodies. Compliance could be maintained in other ways without imposing such restrictions.
- Post-launch compliance should focus on field performance reviews and batch verification processes rather than repetitive studies. This approach would ensure continued maintenance of device performance without the need for repetitive Common Specifications work.

- There was a lack of clarity in the proposal to demonstrate continuous Common Specification compliance. This proposal would exceed the requirements of Regulation EU 2017/746, which only requires manufacturers to reference relevant Common Specifications in their PMPF plan.

Table 6. Question two breakdown by respondent

Respondent	Yes	No	No opinion	Total responses
Overall view	32 (82%)	5 (13%)	2 (5%)	39
Organisations	16 (89%)	2 (11%)	0 (0%)	18
Professionals	12 (70%)	3 (18%)	0 (12%)	17
Individuals	4 (100%)	0 (0%)	0 (0%)	4
IVD Suppliers	18 (90%)	1 (5%)	1 (5%)	20
Class D IVD Suppliers	11 (92%)	1 (8%)	0 (0%)	12
COVID-19 Suppliers	11 (100%)	0 (0%)	0 (0%)	11

The government response

Having considered the views of respondents, and taken into account the concerns outlined above, the government intends to amend the MDR 2002 to incorporate the Common Specifications for certain Class D IVD devices, and to require manufacturers to meet those Common Specifications as a condition for placing their devices on the Great Britain market. Common Specifications will only apply to Class D IVD devices where there is a significant risk associated with the use of the device for public health and patient safety. This is because adoption of the Common Specifications will:

- Improve the safety and quality of certain high-risk IVD devices, such as those for infectious diseases, blood grouping, and tissue typing, by providing more robust and comprehensive requirements for clinical evidence, performance evaluation, and post-market surveillance.

- Provide consistency and harmonisation across Great Britain and Northern Ireland markets, facilitating trade and reducing regulatory burden for IVD device manufacturers.

- Align Great Britain with the international standards and best practices for IVD device regulation, enhancing the UK's reputation and competitiveness in the IVD device sector.

- Benefit the healthcare system and public health by ensuring the reliability of the safety of certain high-risk IVD devices, especially in the context of the COVID-19 pandemic and other emerging health threats.

The government acknowledges the new WHO statement that COVID-19 is now an established and ongoing health issue which no longer constitutes a public health emergency of international concern. However, we maintain our policy position, given the strong agreement from respondents, to introduce Common Specification requirements for COVID-19 tests. Since this is a recent declaration from the WHO, there is still a possibility for a new strain to develop, and so our proposed approach maintains the right balance of precaution and consistency across Northern Ireland and Great Britain. We will continue to monitor COVID-19 infection and intend to classify tests for SARS-CoV-2 appropriately as needed.

Additionally, we will reconsider the classification of COVID-19 tests in guidance, under the classification system that will be introduced by the 'pre-market' regulations currently under development. Further information on the proposed IVD device classification can be found in the consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices.

We understand the concerns raised about including Common Specifications in the PMPF. We recognise that ongoing compliance to Common Specifications requirements can be seen as burdensome for manufacturers. However, these are high-risk IVD devices that have significant health impacts for the public. Therefore, we will continue with our proposal to include Common Specification requirements in the PMPF in the future, which aligns with majority of views from respondents. For clarity, we will not be setting more stringent requirements than what is required in Northern Ireland and the EU for the inclusion of Common Specifications in the PMPF.

Coronavirus Test Device Approvals

Proposal

We also propose to remove from the MDR 2002 the Coronavirus Test Device Approvals (CTDA) process, which was introduced in April 2020 as an interim measure to ensure the availability of safe COVID-19 tests in response to the pandemic. The CTDA process allows manufacturers to place COVID-19 tests on the UK market by undergoing an assessment by the MHRA against certain minimum requirements. We consider that the CTDA process is no longer necessary, as the Common Specifications are more robust and comprehensive requirements for COVID-19 tests than the CTDA process. Therefore, we propose to remove the CTDA process from the MDR 2002, and to require COVID-19 test devices to undergo a conformity assessment by an approved body, meeting the Common Specifications requirements in line with Commission Implementing Regulation (EU) 2022/1107, the EU Common Specifications for certain Class D IVD devices.

Feedback

The consultation invited views on whether the government should remove the requirements for COVID-19 test devices from the MDR 2002, and require COVID-19 test devices to meet Common Specifications requirements. Of the 39 respondents:

- 90% agreed with the proposal
- 8% disagreed with the proposal
- 2% had no opinion

See table 7 for a full breakdown of respondents which includes Class D IVD device suppliers, health professionals, and COVID-19 suppliers.

Respondents who disagreed with the policy proposal were also asked to provide a rationale. The following reasons were given:

- Coronavirus test devices are still new, and it was suggested that they should be treated as a separate entity until there is enough data to prove they can be approved in line with existing devices.
- Better standards are needed; however, approved body oversight is a good idea.
- There was uncertainty about whether the current approved bodies have capacity and/or expertise to assess certain classes of devices effectively. However, this change could come into place once approved bodies have the appropriate expertise.

Table 7. Question three breakdown by respondent

Respondent	Yes	No	No opinion	Total responses
Overall view	35 (90%)	3 (8%)	1 (2%)	39
Organisations	17 (94%)	0 (0%)	1 (6%)	18
Professionals	14 (82%)	3 (18%)	0 (0%)	17
Individuals	4 (100%)	0 (0%)	0 (0%)	4
IVD Suppliers	18 (90%)	1 (5%)	1 (5%)	20
Class D IVD Suppliers	11 (92%)	1 (8%)	0 (0%)	12
COVID-19 Suppliers	11 (100%)	0 (0%)	0 (0%)	11

The government response

Having considered the views of respondents, and taken into account the concerns outlined above, the government intends to remove the CTDA process and introduce Common Specification requirements for high-risk IVD devices. We believe that the Common Specification requirements are more robust and comprehensive than the CTDA process. With regard to capacity to enforce the regulations, the MHRA has oversight of approved bodies and designates them. Therefore, the approved bodies will have the appropriate personnel and expertise and have confidence in their current capacity to assess COVID-19 tests against the Common Specifications requirements. Considering this, we would still propose to remove the CTDA process which was introduced to address the public health risk of COVID-19.

The MHRA believes that the proposed changes would enhance the confidence and trust of the public, the healthcare sector, and the industry in IVD devices, and facilitate their trade and innovation. Furthermore, the proposed changes would support the public health response to infectious diseases, by ensuring the availability of effective and reliable COVID-19 tests.

Next steps

We appreciate the time respondents have taken to consider our proposal and provide feedback. We have analysed the responses to ensure that we understand and address all the issues raised to strengthen our policy position.

We will be taking the following next steps to implement our proposal:

- The government will prepare to amend the Medical Device Regulations 2002 accordingly, in line with the roadmap. In the interim, the government will be introducing an accelerated CTDA process for COVID-19 devices which have CE marking under the EU IVDR.

- The government will provide clear and timely guidance and support to the IVD device manufacturers and suppliers, to help them understand and comply with the new requirements and transition timelines.

- The government will monitor and evaluate the impact of the proposal on the availability of certain high-risk IVD devices and consider any measures to ensure the continued access to these devices.