EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (CORONAVIRUS TEST DEVICE APPROVALS) (AMENDMENT) REGULATIONS 2021

2021 No. 910

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments

2. Purpose of the instrument

2.1 The instrument will create a regulatory requirement for the mandatory approval of diagnostic tests for COVID-19. This will ensure that tests for sale in the UK meet minimum standards in their sensitivity and specificity.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This is the first Statutory Instrument that will be made under section 15 of the Medicines and Medical Devices Act 2021. This instrument amends the Medical Devices Regulations 2002, which were made under section 2(2) of the European Communities Act 1972. This instrument is subject to the draft affirmative procedure and is being made under powers conferred after 21 June 2017. The procedural and publication requirements of paragraphs 13 and 14 of Schedule 8 to the European Union (Withdrawal) Act 2018 therefore do not apply. The statement required by paragraph 15 of Schedule 8 to that Act is set out in the Annex to this memorandum.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the whole of the United Kingdom.

4.2 The territorial application of this instrument is the whole of the United Kingdom.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Innovation, Lord Bethell, has made the following statement regarding Human Rights:

"In my view the provisions of the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 are compatible with the Convention rights."

6. Legislative Context

6.1 Part 4 of the Medical Devices Regulations 2002 (MDR) regulates the placing on the market of in vitro diagnostic medical devices.

6.2 Section 15 of the Medicines and Medical Devices Act 2021 (MMDA) provides that regulations may amend or supplement the MDR in any of the ways specified in

sections 16 to 18. These Regulations are the first Statutory Instrument made under those powers in the MMDA. They will amend elements of Part 4 of the MDR to create a regulatory regime for the mandatory approval of COVID-19 tests in the whole of the UK.

6.3 This mandatory approval requirement will be subject to the enforcement mechanisms provided for in Chapter 3 of Part 4 of the MMDA. In particular compliance notices, suspension notices, safety notices and information notices can be served in respect of breaches (or suspected breaches) of the requirement and failure to comply with any of those notices is an offence under s.30 MMDA.

7. Policy background

What is being done and why?

7.1 The Medicines and Medical Devices Act 2021 provides powers to amend and supplement the regulatory frameworks for human medicines (including clinical trials of human medicines), veterinary medicines and medical devices and thereby enable the effective regulation of these fields going forward following the UK's exit from the EU.

7.2 Testing is a vital part of the United Kingdom's response to COVID-19. The government wants to ensure that test kits sold privately in the UK are of the same high quality as those used by the NHS. This is to avoid undermining national health efforts in containing the pandemic by poorly performing tests giving false results. During public procurement of Lateral Flow Device tests for the NHS only 25% passed through all stages of validation including assessments of performance and quality standards.

7.3 A key part of the government's approach to managing COVID-19 in the long term is to support a thriving private sector market for COVID-19 detection tests, to supplement and support testing led by NHS Test and Trace. The government wants to encourage the private sector to bring a broad range of testing products and services to market to meet the differing needs of businesses and individuals and provide consumer choice. The government is keen to encourage innovation and market growth whilst ensuring tests meet minimum performance standards on which consumers can depend upon.

7.4 Given the urgency presented by the COVID-19 pandemic, a rapid intervention is required to address the quality issue in tests urgently and create a strong regulatory framework so that consumers can buy tests with confidence and without confusion. We have considered and discounted options such as 3rd party conformity assessment due to the time they would take to implement. However, as part of the planned review process we will consider other options again once the immediate market failure has been remedied.

7.5 To this end the UK government is establishing, through this instrument, a requirement that all COVID-19 tests placed on the UK market undergo a mandatory approval process, to validate them as meeting high quality standards. Following a transition period, tests that fail this process would be barred from sale. Retailers, distributors and manufacturers of tests that attempt to sell unapproved tests would face sanction.

7.6 The approval regime that requires persons seeking to bring a test to market in the UK to register via an online portal. They would then submit data for a desk-based assessment to assess their specificity, sensitivity and limits of detection.

7.7 To avoid duplication of work tests supplied by government will be exempt from validation. This is because the market validation is based on the validation DHSC has been doing for public procurement of tests as such these two validation process are judged to be equal. As such DHSC will place tests onto to the market without undergoing the regulatory validation process conducted by DHSC to control access to the UK market.

7.8 Further to avoid potential supply issues in NHS hospitals where a contract exists for the supply of tests, those tests will be grandfathered and exempt solely for the life of that contract to the specific NHS hospital with which their manufacturer has contracted with. This is to avoid potential issues emerging particularly this autumn due to the length of NHS contracts. This means where a pre-existing contract exists, it can continue to be honoured by the manufacturer even if the test has failed validation before all deliveries are completed under the contract. Going forward the improvement to the quality of all tests on the market as they meet the new standard will provide all consumers including public bodies with a better range of tests to choose from in their procurement and avoid the cost of their own assurance processes.

7.9 The results of all tests that pass the validation process will be published providing consumers with a single register of all tests that are on the market, making it easier to make informed decisions when purchasing a test. The register will be available to read in hard copy upon request from DHSC.

7.10 Currently the data collection and analysis used by each manufacturer of COVID-19 tests to achieve its CE marking for COVID-19 tests is unique and designed by each manufacturer. This variability presents significant challenges to consumers comparing the data and acts as a barrier to effective competition.

7.11 Tests in each technology group (either molecular or antigen) that failed to meet the minimum levels of sensitivity and specificity for their technology group would not pass validation and thus would not be allowed for sale in the UK. Manufacturers can seek to improve their tests and resubmit for a fresh validation.

7.12 For those manufacturers with COVID-19 tests already available on the UK market, there will be a transitional arrangement to ensure that those tests can continue to be sold whilst they proceed through the validation process. In order to remain on the market from 1st November 2021 onwards, COVID-19 tests in-scope of this legislation must have been approved through the CTDA process or included on the protocol list, unless otherwise exempt. The current protocol is due to expire on 28 February 2022.

7.13 Manufacturers submitting tests for validation would be liable to pay a standard fee of £14k. These fees are intended to cover the full costs of each validation. The intention is this will be cost neutral by recovering the costs from applicants, so as not to burden the taxpayer, whilst also keeping fees as low as possible. However, we have also provided a discount regime for Small and Medium Enterprises, for which the fee is £6.2K. This is a discount for SMEs of 55% of the total fee which is in line with taxation benefits for research and development spend offered to SMEs.

7.14 The system would be underpinned by the standard enforcement regime for medical devices, so that if unapproved tests were identified they would be removed from sale, and penalties applied to retailers and manufacturers as appropriate. This regime consists of the Medicines and Healthcare products Regulatory Agency's intelligence-led work to ensure manufacturers and distributors are complying with their obligations and the work of local authority trading standards units to keep unapproved

tests out of retailers. The MMDA grants the enforcement authority the power to issue information notices to any person that it believes may have information that it requires in order to determine what further action to take.

7.15 Though the validation process will improve quality standards in specific areas of test performance, it is in addition to and not a replacement of the CE marking standard. As such nothing in these Regulations prevent enforcement agencies acting in their usual way regarding the enforcement of CE marking standards.

7.16 The information notice will require a person to produce records or specified information to the enforcement agency within a set timescale and enable a person appointed by the enforcement authority to take copies of that information. This information will be used to support an evidence led enforcement process.

7.17 The MMDA further empowers the enforcement authority to issue compliance, suspension and safety notices. They will also be able to seize goods such as unapproved tests intended for market. Compliance notices can require manufacturers, retailers or persons involved in supply to take measures to comply with a requirement of this instrument by a specified deadline and to provide evidence they have done so. Suspension notices could be used to temporarily prohibit a business from a range of actions related to supplying a COVID-19 test in order to protect health or safety. Finally safety notices would build on the powers in the suspension notice to also include the power to force a business to publish warnings and run a product recall. These notices will set out the grounds for the action being taken and provide an opportunity for the affected business or person to appeal the notice and its terms.

7.18 The instrument includes a clause that allows the Secretary of State to exempt tests from the approval process on a case by case basis in circumstances which give rise to a need to protect the public from a risk of serious harm to health. The rationale for this clause is as a safety valve in case an unexpected particularly low likelihood but impactful event occurs. For example, that interferes with our ability to validate tests or would interfere with the supply of tests to the NHS.

7.19 COVID-19 testing kits themselves generally do not represent a safety risk to an individual if misused. They can however present a risk to the individual and the general public health as poor information can lead to an infection being missed and the virus spreading. Any impact of this instrument on the safety of the COVID-19 tests will be positive, since it will be providing an independent expert to assess them which will likely observe and report any defects. In addition, it ensures that only tests meeting a minimum standard of accuracy are available on the UK market. It is therefore considered that this instrument does not create any risks for the safety of medical devices. The rigorous validation process ensures test of are of sufficient quality to protect the public health.

7.20 The new regulatory standard will prevent those tests that do not meet the new minimum standard from entering the market. This in theory will reduce the number of tests available to the UK market. However, in reality we are removing tests from circulation that could be a threat to public health due to their higher than tolerable propensity to give false results. The impact that false negative results can have on public health justifies removing them from the market.

7.21 There is no evidence that the type of validation we are imposing, nor the fees or time the process will require, will act as a deterrent to most manufacturers of quality tests, given their experience with dealing with such processes. The upfront fees are in line

with those used for other similarly processes such as conformity assessment both domestically and internationally. However, we recognise that some stakeholders were of the opinion it may present a barrier to SMEs. As such we have set a lower rate for SMEs as defined by the Small Business Enterprise and Employment Act 2015.

7.22 The creation of a highly respected validation process such as the one we have designed could create a market efficiency with high quality tests seeking the UK market and poor quality tests self allocating themselves out, or striving to raise their standards to a sufficient level. In either scenario the supply of high quality tests is unlikely to be impacted.

7.23 The Government anticipates that private sector provided testing will form a crucial part of day-to-day testing as we move into the long-term management of COVID-19. We therefore expect that this will require considerable expansion of domestic production and potentially an increase in imports to ensure there is sufficient supply to meet demand.

7.24 Naturally demand for COVID-19 tests has grown greatly since the start of the pandemic. Both in the UK and around the world frontline medical services like our world leading NHS worked tirelessly to rapidly increase testing capacity on a massive scale. This demand (though less than at the peak of the pandemic) will remain for years to come as a preventative measure through testing and early identification becomes the norm in managing the virus. We expect demand from businesses to test employees and, in certain circumstances, customers. For these reasons, we require a strong private sector capability in testing. Though we expect demand to be for the most effective tests, and thus the market to respond to this over time with an increase in quality, this will take too long to meet our short-term public health requirement as such a market failure currently exists, and regulation can remedy in the short term.

7.25 Currently the USA is the world's leading exporter of tests and China is quickly increasing its production particularly of lateral flow test. This creates a strong global supply in tests. However, the rapid expanse has naturally brought with it bottlenecks, for example demand for raw materials. Regulation can potentially help lead to a more productive sector. By forcing companies to focus on developing high quality tests in order to enter the market, we can expect this to mean raw material and other resources are more efficiently allocated further down the supply chain towards those companies producing higher quality tests. The government is keen to develop a resilient UK based supply chain to safeguard test supply particularly as we strive for improved quality. As imports continue, it will be important that these Regulations apply equally to overseas manufacturers and wholesalers as they do to UK manufacturers and retailers.

7.26 The UK government has a number of objectives in relation to facilitating a thriving private sector market for COVID-19 detection testing. One key objective is about enabling and supporting innovation. We are keen to grow the private testing market, enabling domestic innovation to improve testing effectiveness and efficiency. The faster and more accurate tests become the easier it is to prevent the spread of infection. The UK government is keen to leverage the UK's world-renowned capabilities in medical technologies to become a world leader in the development and manufacture of COVID-19 tests. We know many companies in the UK are focusing on developing faster and more innovative testing solution as we have already seen with the development of LAMP and LamPORE tests.

7.27 As we need tests to meet a sufficient quality in order to be effective, the approval requirement imposed by this instrument will only prevent poor quality tests entering the market.

7.28 For a market to function efficiently it requires all parties to have access to information to make rational decisions. The requirements imposed by this instrument will make the UK private testing market more competitive, as manufacturers will need to improve the accuracy and speed of their tests in order to outcompete competitors, this should continually drive innovation as well as acting as a downward pressure on prices. We do not believe validation will significantly reduce the supply of high quality COVID-19 tests on the UK market. As such, the benefits from improvement in consumer information, test quality and assurance outweigh the negligible risk of a reduction in supply.

7.29 The government does not believe this instrument will deter any business from researching or manufacturing COVID-19 tests in the UK.

7.30 It may dissuade suppliers of low quality tests from bringing stock to the UK, however we do not consider this to be a negative impact but a positive as we wish to focus our market solely on high quality tests.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act

9. Consolidation

9.1 This instrument will amend the Medical Devices Regulations 2002. This instrument will not seek to consolidate that instrument.

10. Consultation outcome

10.1 The MMDA requires that, before making regulations under s.15, a public consultation be carried out. A four week consultation was launched in April 2021. Over forty responses were received which included responses from: large and small manufacturers, chemists, retailers, trade associations, professional bodies, local authorities, universities and individual experts. The government has now published its response to the consultation available at http://www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation/outcome/private-coronavirus-covid-19-testing-validation-government-response

10.2 The results of the consultation showed strong support for the policy aim, with over three quarters of respondents supporting the need to give assurance on the performance of COVID-19 tests, above and beyond CE marking. Over three quarters agreed with the Secretary of State's assessment that a validation regime would improve the safety of devices. Similarly more than two thirds agreed that these Regulations would not reduce the supply of high-quality tests and over half of respondents agreed that it would help make the UK an attractive place to research, supply and manufacture tests.

10.3 Two key concerns raised by stakeholders were that the proposed fees could act as a barrier to entry for SMEs, and that some tests have already passed rigorous validation such as those approved for UK public procurement. We have acknowledged both

concerns. The government does not want to create any unnecessary barriers to entry to the COVID-19 testing market, nor does it want to require onerous or repetitive work for validation. As such we are have put lower fees for qualifying SMEs into the Statutory Instrument to lessen the burden on SMEs. Similarly, we will ensure the validation process can use existing evidence where our scientists are satisfied it is of sufficient quality to avoid any duplication and we are exploring implementing a lighter touch expedited verification process in such cases.

10.4 We have sought to work closely with colleagues in the Devolved Administrations (DAs) and we have engaged on a weekly basis with officials and shared drafts of the regulations for their input. Their contributions have been taken on board and incorporated into the regulations.

11. Guidance

11.1 DHSC is developing guidance to support manufacturers so they fully understand how the validation process will work and what will be required of them at each stage. The Government will seek to ensure there is a high level of awareness of the validation regime particularly amongst manufacturers and retailers. The success of the consultation has provided a strong base for further engagement. Draft guidance to support Parliamentarians in their scrutiny will be published in draft at https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview

12. Impact

12.1 The impact on business is that mandatory validation will create additional costs for manufacturers of COVID-19 molecular and antigen tests. This is in terms of administrative work in registering and generally participating in the validation process; fees payable at each stage of the validation process; and foregone profits for manufacturers not applying or whose products do not pass validation.

12.2 Demand for test kits left unmet by the withdrawal of products failing validation, or those not presented for validation, is expected to be fulfilled by the expansion of supply of products that do pass validation. The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products.

12.3 There is a risk that programme costs will be passed onto consumers. However, the price rise is expected to be low given the current value of the market and number of manufacturers. Adding a worst-case £70m of programme costs into a £3.7bn market and assuming this is passed onto consumers suggests prices rise by around 2%.

12.4 The policy will bring about direct benefits in improved performance and reliability of COVID-19 tests. More specifically reducing the number of false negative results and increasing the number of true positive results, correctly identifying those carrying COVID-19, reducing onwards infections and improving wellbeing, long-term health, mortality and socioeconomic engagement.

12.5 Furthermore, improved test performance will reduce the number of false positive results and increase the number of true negative results, removing unnecessary constraints on socioeconomic engagement, improving productivity and wellbeing of test participants.

12.6 There is no, or no significant, impact on charities or voluntary bodies. Charities or voluntary bodies involved in combating COVID-19 both in the UK and overseas will more easily be able to identify high performing tests to buy. This will reduce administrative burden in researching test kits to ascertain their quality.

12.7 There is no, or no significant, impact on the public sector given the expected absence of price increases. The impact on the public sector is that DHSC will be required to provide additional resource in order to process applications through validation as the delivery body. The MHRA may also experience an increase in cases to investigate to ensure compliance.

12.8 An iteration of the Impact Assessment was published 20 July 2021 and is available at https://www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation

12.9 An updated iteration of the Impact Assessment was published 10 February 2022 and is available at https://www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 To minimise the impact of the requirements on small businesses (employing up to 250 people), we have provided lower fees for small business to prevent fees becoming a barrier to entry.

13.3 This decision was taken following stakeholder feedback in the consultation and the assessment that this fees discount would facilitate new and existing SMEs to enter the market.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is to monitor this regulatory regime on an ongoing basis to ensure it remains fit for purpose. The quickly changing nature of both the underlying public health policy issue presented by the COVID-19 pandemic and the market for private testing necessitates this approach. We will engage closely with stakeholders to ensure regulation remains agile and doesn't present unforeseen and unnecessary burdens on business. As conditions change, we will look again at some of the options that did not work in the immediate term to see if they are now more suitable to address the market situation. We will also consider developments internationally particularly if there are benefits in aligning with other regulatory jurisdictions in the longer term. We will also want to capture learning more generally to help in our preparation for future pandemics.

14.2 A statutory review clause is included in the instrument. This will require the Secretary of State to publish a report before 31 December 2022 assessing:

- the effectiveness of the validation regime to ensure minimum quality levels for COVID-19 test kits,
- the impact on prices for consumers and consumer confidence,
- impacts on safety and supply of COVID-19 tests, and
- the impact on the UK as being a good place to research and manufacturer COVID-19 tests.

14.3 The report will be published with copies placed in the Libraries of both Houses of Parliament. The review clause does not require a periodic review and in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Lord Bethell has made the following statement:

"In my view, it is not appropriate to include a clause in this instrument that would require a periodic review. This is because there is already a requirement in section 46 of the Medicines and Medical Devices Act 2021, which will require the operation of these Regulations to be reviewed every 24 months."

15. Contact

15.1 Jon Doyle at the UK Health Security Agency email: jon.doyle@dhsc.gov.ukcan be contacted with any queries regarding the instrument.

15.2 Harry Mayhew, Deputy Director for Private Sector Testing, at the UK Health Security Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Maggie Throup MP, the Parliamentary Under-Secretary of State for Vaccines and Public Health at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018 and the European Union (Future Relationship) Act 2020

Part 1A

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before IP completion day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal	Sub-paragraphs (3) and (7)	Ministers of the Crown	Set out the 'good reasons' for creating a

offences	of paragraph 28, Schedule 7	exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising section 8 or part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before IP completion day, and explaining the instrument's effect on retained EU law.

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees

Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

1. Explanations where amending or revoking regulations etc. made under section 2(2) of the European Communities Act 1972

1.1 The Minister Lord Bethell has made the following statement regarding regulations made under the European Communities Act 1972:

"In my opinion there are good reasons for the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 to amend the Medical Device Regulations 2002. This is because it is proportionate and necessary to address the market failure of in vitro diagnostic Covid 19 tests being of insufficient quality. This presents a clear and present public health risk that must be addressed. The Medical Devices Regulations 2002 set out the requirements that must be met before an in vitro medical device (which includes a Covid-19 test) can be placed on the UK market.

Those regulations are retained EU law because they were made under section 2(2) of the European Communities Act 1972 (as well as section 56 of the Finance Act 1973, and sections 11 and 27 of the Consumer Protection Act 1987); and were made to implement three EU Directives, including Directive 98/79/EC on in vitro diagnostic medical devices. This instrument amends the Medical Devices Regulations 2002 to insert an additional approval requirement that must be met before Covid-19 tests can be placed on the market and supplied in the UK. Amending the Medical Device Regulations 2002 is the most sensible way to impose new regulatory requirements for Covid-19 tests and address the immediate issue in the context of the ongoing pandemic since 2020. The amendments made by this instrument will place UK regulation on a more stringent footing than the current approach taken by the EU.".