



INNOVA MEDICAL GROUP INC

Justification for the choice of the Negotiated Procedure Without Prior Publication of a Call for Competition in accordance with Article 32

1. On 11 March 2020 the World Health Organisation declared a COVID-19 pandemic with the associated serious risk posed to life. The UK Government's response to the national emergency posed by COVID-19 includes the putting in place by it of arrangements for large-scale testing in respect of COVID-19.
2. As part of those arrangements, it needs to acquire products in order to implement the large-scale testing programme necessary to build a profile of the spread of COVID-19 and to prevent further loss of human life, to allow the population to return to work safely. Relevant to its procurement strategy is the efficient use of lateral flow test devices for self-use throughout the UK.
3. Accordingly the UK government will be fulfilling a significant volume of its overall requirement for home testing by using lateral flow devices developed by Innova.
4. DHSC is satisfied the relevant tests permitting use of the negotiated procedure without prior publication (Regulation 32(2)(b)(ii)) are met:
 - a. The works, supplies or services can be supplied only by a particular economic operator as competition is absent for technical reasons: Innova are the only available supplier of home use lateral flow tests for COVID-19 as there is currently no other supplier whose COVID-19 tests are authorised by the relevant regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), for self-test use in the UK.
 - b. No reasonable alternative or substitute exists: there is currently no other supplier of lateral flow devices that has MHRA authorisation for the self-test use needed to satisfy DHSC's requirement.
 - c. The absence of competition is not the result of an artificial narrowing down of the parameters of the procurement: this procurement is part of a procurement strategy by the UK government to increase testing capacity to meet demand due to the COVID-19 pandemic as the country exits from lockdown.