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Department of Health and Social Care (DHSC)
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MHRA
10th Floor, Devices Division
10 South Colonnade
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www.gov.uk/mhra

22nd December 2020

Our Ref: DEU/012/2020/003

Dear ██████████

MEDICAL DEVICES REGULATIONS 2002
AUTHORISATION OF SPECIAL USE OF DHSC COVID-19 Self-Test Kit

I refer to your e-mail dated 14/12/2020 in which you requested special approval to supply the above non-CE marked medical devices on the UK Market, on the basis that a duly justified request has been made and this is in the interests of the protection of health. The reasons for the application cited *“This submission is for an antigen based self-test swab kit which we believe is critical for the National Testing Programme in order to scale up our testing capability and bring testing to communities and groups without current easy access to testing to identify individuals that are infectious with COVID-19”*.

Based on this confirmation, the Secretary of State acting as the MHRA is satisfied that the request is duly justified, and that it is in the interests of the protection of public health to authorise the supply of the device under regulation **39(2) IVD** of the Regulations, subject to the conditions set out below:

This authorisation commences on 22/12/2020 and ends on whichever of the following dates occurs soonest:

- a. 22/06/2021;
- b. the date when the device is CE marked; or



- c. the date when sufficient quantities of CE marked alternative product is available on the market.

If this authorisation ends on 22/06/2021, and there continues to be a need for a further authorisation, the position will be reviewed by the MHRA and a decision taken on whether it remains in the interests of the protection of health for a further authorisation or an amendment to this authorisation to be made.

2. This authorisation is solely for the use in the testing of large sections of the population to detect infection in asymptomatic individuals. We do not currently support the use of the test for a 'test to enable' function until we are satisfied there is evidence to support this.
3. This authorisation is solely for the use of Innova tests as reviewed by MHRA. DHSC must inform MHRA prior changing any of the components of the devices.
4. That the devices are fit for the purpose intended, will work as intended in line with stated performance and have been assessed as such.
5. That the plan for distribution and roll-out is shared with MHRA.
6. That MHRA will agree to the content of the Instructions for Use before the devices are being rolled-out, ensuring that:
 - a. Any mentions about 'Negative results' should be clarified to explain that a negative result does not exclude the possibility of exposure or infection and the individuals should continue to follow their local guidance on social distancing;
 - b. The Instructions for Use are to be made available in other languages before rolling out. Access to testing should be inclusive and address those individuals who may not be able to read or write;
 - c. The leaflet must contain details regarding the original manufacturer of the devices;
 - d. The leaflet must contain the current version number and, in any event, the review date;
 - e. The commentary in the video states "relief from having a negative result" is misleading and must be modified accordingly;



7. That the recipients of the devices in question are supplied with the necessary instructions for use.
8. That you agree to the details of the authorisation being listed on [MHRA's website](#) to confirm the manufacturer & products authorised under this exemption including the issue date and duration.
9. That you submit to the MHRA a detailed time plan for CE marking of the device, or explanation as to why you will not be seeking CE marking.
10. That once every two weeks you submit to the MHRA a report detailing, a summary of adverse incidents whilst under this authorisation, the number of devices supplied and to whom; the manufacturer must keep track of every device down to the end user through their distribution network. This must be included in the report to MHRA.
11. That the manufacturer has in place or puts into place mechanisms for monitoring the performance of the devices supplied under these conditions.
12. That you will cease supply of the above devices when CE marked stocks become available.
13. That at the end of the above period or when CE marked alternative supplies of the device become available the devices supplied by the authority of this authorisation will be returned to you or destroyed unless a further derogation is granted.
14. That supply of the devices is only permitted by the Department of Health and Social Care as part of their planned deployment of COVID-19 tests in the UK.
15. That the DHSC shall conduct suitable verification prior to deployment of the tests.
16. That within three weeks you submit plans for a post market performance study to collect further evidence of clinical and analytical performance.
17. DHSC must have a Post market Surveillance plan and Quality Management System to collect and evaluate any complaint received in relation to compromised safety, quality or performance of the device and undertake the necessary corrective and preventive actions such initiating and undertaking recall of products if a safety action is identified.

That within three weeks, you submit a detailed performance surveillance plan for monthly reports to MHRA to include the following:



- a. Results and conclusions of the analyses of the post market surveillance data gathered as a result of the post market surveillance plan (e.g. report of ALL complaints plus report of those considered to be reportable as vigilance);
 - b. A rationale and description of any preventive and corrective actions taken;
 - c. The conclusions of the benefit-risk determination;
 - d. The main findings of the post market performance study;
 - e. The volume of the devices and an estimate of the size and other characteristics of the population using the device and the usage frequency of the device;
 - f. A report of own participation in ISO17043 accredited EQA/PT schemes;
 - g. A report from EQA/PT scheme when available for their kit's performance overall;
 - h. Regular use of controls;
 - i. Regular use of blinded sample panel (when available).
18. That DHSC implements a Proactive Post Market Surveillance plan to survey user experience to monitor events such as:
- a. Material break (if something breaks during use);
 - b. Detachment of device component (for example, if the swab head of the swab falls off);
 - c. Component missing (if something in the kit is missing);
 - d. Packaging problem;
 - e. Unable to obtain readings (e.g. failure of control line or if the user is unsure of the result);
 - f. Failure to obtain sample;
 - g. Inadequate instructions;
 - h. Device handling problem, i.e. the opening and emptying of the of the buffer solution container;
 - i. Negative clinical effect associated to the test, e.g. cuts, nose bleeds etc;
 - j. Including Details of the test kit (e.g. brand name/model, Lot/batch, barcode number) to help with traceability when investigating incidents;



19. That you agree to provide full details of any adverse incidents that occur in relation to the device or the use of the device in addition to the normal procedures for reporting such incidents to the MHRA.

20. That DHSC agrees to provide details to the users that any adverse incidents that occur in relation to the device or the use of the device are reported via the Yellow Card Scheme, specifically the 'healthcare professional report form' found at: <https://yellowcard.mhra.gov.uk>

Please take this letter as formal approval. Please contact Devices.ExceptionalUse@mhra.gov.uk if you require any clarification in relation to this process.

Yours sincerely



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