Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10th Floor, Devices Division
10 South Colonnade
London
E14 4PU

www.gov.uk/mhra

21st December 2020

Our Ref: DEU/011/2020/004

Dear [redacted]

MEDICAL DEVICES REGULATIONS 2002

AUTHORISATION OF SPECIAL USE OF SARS-CoV-2 end-point PCR Diagnostic Test System

I refer to your e-mail dated [redacted] 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 [redacted]

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:

1. This authorisation commences on 21/12/2020 and ends on whichever of the following dates occurs soonest:

a. 21/03/2021;

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 21/03/2021, 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. That the devices are fit for the purpose intended, will work as intended in line with stated performance and have been assessed as such;

3. That the hospitals and/or laboratories in question are supplied with the necessary instructions for use;

4. That the current inclusion criteria for testing is clarified and included in the documentation;

5. 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.

6. 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;

7. That you submit to the MHRA a monthly 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.

8. That the manufacturer has in place or puts into place mechanisms for monitoring the performance of the devices supplied under these conditions;

9. That you will cease supply of the above devices when CE marked stocks become available;

10. 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;

11. That supply of the devices is only to hospitals and/or laboratories agreed with the Department of Health and Social Care as part of their planned deployment of COVID-19 tests in the UK;

12. That the hospitals and/or laboratories in question shall be instructed to conduct suitable verification prior to deployment of the devices, and provided with assistance to do this where appropriate;

13. That you successfully assess the assay against the CE Marked control material and provide the results to MHRA within 4 weeks;

14 [redacted]

15. That within 4 weeks you submit plans for a post market performance study to collect further evidence of clinical and analytical performance;

16. That within 4 weeks, you submit a detailed performance surveillance plan for monthly reports [see condition 7] 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 sales of the device 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 accredited EQA/PT schemes

g. A report from EQA/PT scheme for the device performance overall

h. Regular use of CE marked assay controls

i. Regular use of blinded sample panel (when available)

17. That you agree to provide details of any adverse incidents that occur in relation to the device or the use of the device 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

[redacted]

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