



Medicines & Healthcare products  
Regulatory Agency



Mr Ioan Wigley  
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**MHRA**  
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[www.gov.uk/mhra](http://www.gov.uk/mhra)

14<sup>th</sup> January 2021

Our Ref: DEU/012/2020/006

Dear Mr Wigley

**MEDICAL DEVICES REGULATIONS 2002**  
**AUTHORISATION OF SPECIAL USE OF COVERSCAN MD**

I refer to your e-mail dated 31 December 2020 in which you requested special approval to make available the above non-CE marked medical device, 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 as,

- *“there is growing evidence that a certain percentage of patients with COVID-19 will suffer from heart, lung, kidney and pancreas damage from their infection. Additionally, patients who already suffer from decreased heart function, metabolic diseases or chronic kidney disease may be at greater risk of severe illness from COVID-19. Identifying multiple organ complications is therefore an important part of the clinical management pathway for COVID-19 patients. Screening tools that allow a quick, repeatable, simultaneous evaluation of multiple organs are becoming increasingly relevant for the now many thousands that have been affected by 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 putting into



service of the device under regulation **12(5) General MDs** of the Regulations, subject to the conditions set out below:

1. This authorisation commences on **14<sup>th</sup> January 2021** and ends on whichever of the following dates occurs soonest:
  - a. **14<sup>th</sup> July 2021**;
  - b. the date when the device is CE marked; or

If this authorisation ends on **14<sup>th</sup> July 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 employees of Perspectum Ltd will be the only authorised users. The MHRA will consider amendments to this where necessary
4. That the devices will not be used under this authorisation until the company is fully registered with the Care Quality Commission
5. That the users are supplied with the necessary instructions for use;
6. 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.
7. 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;
8. That you submit to the MHRA a monthly report detailing, a summary of adverse incidents whilst under this authorisation;
9. That your company has in place or puts into place mechanisms for monitoring the performance of the devices used.



10. That at the end of the above period or when CE marked alternative supplies of the device become available, the Coverscan MD must be taken out of clinical use unless a further extension to the derogation is granted
11. That your company agrees to provide full details of any adverse incidents that occur in relation to the use of the device in addition to the normal procedures for reporting such incidents to the MHRA.

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

Yours sincerely

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