Unit 9, Fusion@Magna
Rotherham
S60 1FE

24th March 2020

RE: COVID-19 PANDEMIC, INFECTION CONTROL DEVICES

Dear sir/madam,

I write to you in an urgent capacity regarding the provision of medical devices critical to the fight against the Covid-19 pandemic. Delays in obtaining regulatory approval for medical devices could prevent critical devices being made available to patients who need them. We must act now to avoid this problem.

I spent 14 years working as a frontline NHS doctor and founded my company Mantra Medical Ltd to develop infection control innovations. Our devices are now highly relevant because they address infection spread via pulse oximeters and blood pressure cuffs - clinical tools used in the assessment of every hospital patient. Unless urgent action is taken, these tools will transmit the coronavirus to patients on a massive scale. Our innovations could eliminate this problem and have the potential to save many lives. However, our devices do not yet have a CE-mark and cannot be made available to patients without government support. I need your help to ensure that our devices reach patients without delay.

I write to you to seek your support in obtaining permission to derogate from the normal medical device conformity assessment procedures under Article 59 MDR 2017/745.

As you are aware, the coronavirus is highly infectious and transmits through contaminated surfaces as well as through air. The risk of healthcare-associated transmission is extremely high. Vital patient interactions such as measuring oxygen levels, pulse rate and blood pressure now represent an obvious danger to patients because the tools that perform these measurements act as a source of coronavirus transmission. Pulse oximeters and blood pressure cuffs contact multiple patients every day, often in quick succession. To prevent them transmitting the infection they must be cleaned between every patient; something that is impractical with existing cleaning methods. By contrast, our innovations will ensure consistent cleaning of pulse oximeters and blood pressure cuffs between every patient with no disruption to staff workflow. This is an entirely unique capability that could be lifesaving in the context of the coronavirus pandemic.

Our devices are currently separated from the market by the lengthy conformity assessment

procedures normally required to gain a CE-mark. This will prevent the devices being a part of the fight against the coronavirus outbreak. In our view, these devices are needed immediately, as well as in the future to prevent other seasonal and ongoing infectious risks.

Fortunately, the Medical Device Regulations MDR 2017/745 provides a potential solution for which I will need your support. Article 59 MDR allows for emergency derogation from standard conformity assessment procedures in the event of a public health crisis, but only with competent authority approval. If you agree that preventing infection spread through two of the most common patient interactions could save lives, I would respectfully request the following:-

- Contact the Secretary of State for Health and Social Care and urge him to approve our application to the MHRA, the UK's competent authority
- Contact the MHRA to urge them to review and approve our application with speed
- Contact NHS England to encourage a streamlining of procurement processes to ensure availability of critical devices at this time of great need.

We are faced with an unprecedented public health emergency and it is incumbent upon me as a doctor to do everything I can to help. Working together with healthcare providers, manufacturers and the wider medical device community, our innovations will integrate into existing infection prevention methods to help reduce disease transmission.

I have contacted the MHRA and the Secretary of State for Health and Social Care directly with this request. I am also copying this letter as a courtesy to my MP, Nick Fletcher, and to Mr Dan Jarvis, the Mayor of the Sheffield City Region, because my office is located in that Region.

I would be pleased to discuss this matter with you at any time if you thought this appropriate. If you would like more information about the devices and their functionality then please feel free to contact me at any time through any of the routes below.

Yours faithfully

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