

Office of the Clinical Lead Antimicrobial Resistance and Infection Control Team Office of the Chief Clinical Officer HSE Merlin Park Hospital Galway H91 N973

hse.ie/hcai

28<sup>th</sup> November 2022

Re: Dobu mask 700 Type IIR surgical mask

**Dear Colleagues** 

We have been notified thatthe Health Products Regulatory Authority (HPRA) has granted the HSE a Regulatory Derogation (pursuant to Article 59 of Regulation (EU 2017/745) to allow the use of Dobu mask Type IIR surgical mask, a non CE marked medical device. This product is currently available from HSE via the National PPE Supply Chain.

This derogation was granted following an application to HPRA by the HSE and the manufacturer. HPRA were satisfied that the product meets all required testing and standards.

"All healthcare professionals using this medical device should be informed that it has been placed on the market under a regulatory derogation" (HPRA).

This information will be made available via www.hse.ie.

For procurement related queries for these or other products please contact: Covid19.procurement@hse.ie

Regards,

**Dr. Eimear Brannigan**, Clinical Lead, HSE AMRIC Martin Quinlivan, National PPE Team HSE Procurement