Guidance on international manufacture and regulatory approval

This CPAP has been approved for manufacture by UCL by UK regulators, the Medicines and Healthcare products Regulatory Agency (MHRA) under special conditions. These conditions state that this is a non-CE marked CPAP, given approval for use in the NHS for the interest of public health protection under the Covid-19 pandemic emergency. Please note that UCL's MHRA approval is time limited and ends on whichever of the following dates occurs soonest:

a) 1st October 2020;

b) The date when the device is CE marked; or

c) There is no longer a need for the device in the treatment of COVID-19 patients.

Any manufacture and use of this CPAP by third parties **must require the third party to have local regulatory approval in place**, as required in the third party's own country and must fully comply with any stipulated conditions, laws and regulations that ensure full patient safety.

Relevant resources:

World Health Organisation (WHO) guidance on resource planning for COVID-19, including critical items (PPE, diagnostic equipment, clinical care equipment) is available here: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items

World Health Organisation (WHO) technical specifications for invasive and non-invasive ventilators for COVID-19: https://apps.who.int/iris/bitstream/handle/10665/331792/WHO-2019-nCoV-Clinical-Ventilator_Specs-2020.1-eng.pdf

UK National Health Service (NHS) guidance for the role and use of non-invasive respiratory support (including CPAP) in adult patients with COVID-19 is available here: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/specialty-guide-NIV-respiratory-support-and-coronavirus-v3.pdf

Further UK guidance on the use of personal protection equipment (PPE) is available here: https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control