
Provisional Authorisation for Ventilators

<i>Date of provisional authorisation</i>	13 July 2020
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<i>Applicant</i>	Advanced Bio Machines Pte Ltd
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<i>Name of device</i>	ABMRC Alpha Basic and Alpha Plus Ventilators
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<i>Intended purpose (As per manufacturer's instructions for use)</i>	<p>The Alpha Ventilator is intended for continuous ventilation support of patients:</p> <ul style="list-style-type: none">– In hospitals, alternate care settings– by qualified, trained personnel under the direction of a physician– of adult and paediatric (>10 kg) patients with reduced lung function who are dependent on ventilatory support, such as acute respiratory failure, acute or chronic respiratory insufficiency– either invasively or non-invasively– that may be life-supporting, provided that emergency equipment (resuscitation bag) is available– with supplemental oxygen through a low flow inlet port of up to 30lpm
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