

Provisional Authorisation for Decontamination Medical Devices

<i>Date of provisional authorisation</i>	07/07/2020
<i>Applicant</i>	Bioquell Asia Pacific Pte Ltd
<i>Product owner</i>	Bioquell UK Ltd
<i>Name of device</i>	Bioquell Hydrogen Peroxide Vapour Generators (BQ50, ProteQ, L4, Q10, Z/Z2, Clarus C)
<i>Intended purpose</i>	<p>For the decontamination of <i>compatible</i>* N95 or FFP2 respirators for single user reuse by healthcare personnel.</p> <p>*<i>Compatible</i> respirators here refer to respirators that do not contain cellulose based material.</p> <p>Single user reuse means the decontaminated mask should be returned to the same user for reuse.</p>
Validated Parameters	
<i>Mass of sterilant in an enclosed space</i>	15 g/m ³
<i>Maximum no. of decontamination cycles (per respirator)</i>	20
<i>Maximum no. of respirators per cycle</i>	<p>2500 respirators</p> <p><i>Respirators, hung from a support or presented on a wire shelving rack, should be sufficiently spaced to prevent contact between respirators. The support should aim for minimal contact with the respirators.</i></p>
<i>Dwell time</i>	10 minutes
<i>Room size</i>	<p>28 m³*</p> <p><i>*Based on validated parameters Room size $\geq 10\text{m}^3$ up to 100m^3 may be used in accordance to recommended dosage of 15 g/m^3</i></p>
<i>Aeration</i>	180 minutes
<i>Sterilant (%)</i>	Bioquell 35% Hydrogen Peroxide (HPV-AQ)
<i>Chemical indicators/ Biological indicators</i>	<p>Bioquell Room CI</p> <p>Bioquell Biological Indicator</p>