



Potential Supplier Questionnaire
Ventilators

Life Sciences Hub Wales Ltd is not an authority on regulatory requirements for the supply of products to the health sector. Buyers are still required to adhere to regulatory requirements: [Gov.uk/guidance](https://www.gov.uk/guidance). Our role is to obtain information on behalf of buyers across Wales to accelerate potential supply opportunities.

Product List	What Products are you able to provide
Product Claims	Please detail the claims that you are making for these products
Regulatory Legislation	State which legislation these devices are regulated under. Eg: MDD, MDR.
Product Classification	What is the classification of the device? For example under the MDD, Class I, IIa, IIb or III ?
Regulatory Compliance Documentation	Either provide copies of: <ul style="list-style-type: none">▪ relevant documentation demonstrating compliance with the MDD/MRD, or▪ submit the approval from Department of Health and Social Care (DHSC), or▪ submit the derogation letter from the MHRA.

Quality Management Systems (QMS)	Please give details of any QMS you have in place. In general ISO 13485 certificate in preference to ISO 9001 is sought
Relevant Standards	<p>Please refer to:</p> <p>https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification/rapidly-manufactured-ventilator-system-specification</p>

In the event that a potential supplier is not in a position to satisfy these requirements, they should first check the Government specifications needed - [gov.uk/government/specification for ventilators](https://www.gov.uk/government/specification-for-ventilators), then contact the DHSC for their approval - ventilation.challenge@dhsc.gov.uk.