Hwb Gwyddorau Bywyd Cymru
Life Sciences Hub Wales

Potential Supplier Questionnaire
Surgical Masks

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. 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? e.g. Type I, Type II or Type IIR face masks
Product Claims	Please detail the claims that you are making for these products
Regulatory Legislation	State which legislation these devices are regulated under E.g.: MDD, MDR, PPE. Note that some may be dually regulated under PPE and 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	Please provide copies of relevant documentation demonstrating compliance with the MDD/MDR. If you are not already compliant, do you have a derogation letter from the MHRA? If so, please provide that instead.

Quality Management Systems (QMS)	Please give details of any QMS you have in place. In general ISO 13485 certificate in preference to ISO 9001 for medical devices is sought
Relevant Standards	Please provide test report and accompanying test certificates showing compliance to EN 14683 :2019 (medical face masks).

In the event that a potential supplier is not in a position to satisfy these requirements, they can submit a request for exemptions and relaxations to MHRA devices.compliance@mhra.gov.uk