

Potential Supplier Questionnaire
FFP 1/2/3 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](https://www.gov.uk/guidance). Our role is to obtain information on behalf of buyers across Wales to accelerate potential supply opportunities.

Product List	<p>What Products are you able to provide?</p> <p>For example, FFP1, FFP2, FFP3 masks</p>
Product Claims	<p>Please detail the claims that you are making for these products</p>
Regulatory Legislation	<p>State which legislation these devices are regulated under. Eg: MDD, MDR, PPE.</p> <p>Note that some may be dually regulated under PPE and MDD/MDR</p>
Product Classification	<p>What is the classification of the device? For example, under the MDD, Class I, IIa, IIb or III?</p> <p>If it falls under PPE regulations then which Category does it fall under (I, II or III)</p>
Regulatory Compliance Documentation	<p>Please provide copies of relevant documentation demonstrating classification compliance with PPE.</p> <p>If the device is not CE marked, provide the authorisation from your Notified Body to place on the market without a CE mark</p>

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	<p>Please provide test report and accompanying test certificates showing compliance to EN 149:2001+A1:2009.</p> <p>This may also include filter testing to EN 143:2000</p>

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 the Department for Business, Energy and Industry Strategy (BEIS) - OPSS.enquiries@beis.gov.uk or devices.compliance@mhra.gov.uk if a medical device.

Useful resources:

- <https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak#personal-protective-equipment-ppe>
- Commission recommendation: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H0403&from=EN>
- EC FAQ: <https://ec.europa.eu/docsroom/documents/40521>
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