



Potential Supplier Questionnaire
Reusable Half-Mask with Filter

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? e.g. half mask with P1, P2 or P3 filter
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 PPE, category I, II or III?
Regulatory Compliance Documentation	Please provide copies of relevant documentation demonstrating classification compliance with PPE If the device is not CE marked, provide the authorisation from your Notified Body to place on the market without a CE mark

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 reports and accompanying certificates showing compliance to EN 140:1999 for the reusable half mask and EN 143:2000 for the filter testing

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.

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>