Hwb Gwyddorau Bywyd Cymru
Life Sciences Hub Wales

Potential Supplier Questionnaire
Protective Eyewear (including Goggles and Visors)

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?
Product Claims	Please detail the claims that you are making for these products In particular, please explain what level of protection they are intended to provide to the wearer
Regulatory Legislation	State which legislation these devices are regulated under E.g.: MDD, MDR, PPE, Biocide or medicinal product. Note that some may be dually regulated under PPE and MDD/MDR
Product Classification	What is the classification of the device? If it falls under PPE regulations then which Category does it fall under (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 for medical devices, is sought but ISO 9001 may be acceptable for PPE Note there is an expectation that the manufacturer has a QMS in place to ensure the safety and performance of each device
Relevant Standards	Do you have data showing compliance with any elements of the following standards? ・ BS EN 166:2002 Personal eye-protection - Specifications ・ BS EN 167:2002. Personal eye protection. Optical test methods. ・ BS EN 168:2002. Personal eye-protection. Non-optical test methods. What material is used for each component which will be in contact with the wearer's body? Is it medical grade? Do you have biocompatibility data according to BS EN ISO 10993 Biocompatability parts 1, 5 (cytotoxicity) and 10 (Tests for irritation and skin sensitization)?

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