



Potential Supplier Questionnaire
Hand Sanitisers

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, 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? For example: cosmetic, biocide, medical device or medicine.
Regulatory compliance documentation	Please provide copies of documentation to show the following: <ul style="list-style-type: none">▪ Cosmetic - notification to Cosmetics Products Notification Portal (CPNP).▪ Biocide - "Certificate of Simplified Authorisation" or "Certificate of Authorisation".▪ Medical device - compliance with the relevant classification of the MDD.▪ Medicine - proof medicine is licenced.

	<p>Note that the HSE Biocide regulations for hand sanitisers have been updated for COVID-19:</p> <ul style="list-style-type: none"> ▪ If the hand sanitiser contains ethanol and meets the WHO specified formulation <p>https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf)</p> <p>When product authorisations for the UK market are no longer required. Please therefore submit evidence of compliance with the WHO formulation</p> <ul style="list-style-type: none"> ▪ If the hand sanitiser contains propan-2-ol there is a WHO specified formulation available. Derogation from HSE is required for this. <p>- If the hand sanitiser contains propan-1-ol no WHO specified formulation exists. Derogation from HSE is required for this.</p>
Quality Management Systems (QMS)	Please give details of any QMS you have in place
Relevant standards	<p>Please provide test report and accompanying test certificates showing compliance to BS EN 14476 against enveloped viruses.</p> <p>If appropriate to your claims, also provide test report and accompanying test certificates to BS EN 1500</p> <p>If appropriate to your claims, also provide test reports and accompanying test certificates to BS EN 1276, 1275, 13727, 13624 (bacterial/fungal solution methods).</p> <p>If appropriate to your claims, also provide test reports and accompanying test certificates to BS EN 14999 Hygiene Hand wash</p> <p>If appropriate to your claims, also provide test reports and accompanying test certificates to BS EN 14348 (mycobactericidal method)</p>

In the event that a potential supplier is not in a position to satisfy these requirements, information on HSE exemptions and relaxations can be found here: [hse.gov.uk/news/hand sanitiser](https://hse.gov.uk/news/hand-sanitiser)