

The Office for Product Safety and Standards

Enquiries: +44 (0)121 345 1201

BSI Assurance UK Ltd
SGS United Kingdom Limited
SATRA Technology Centre Ltd
Shirley Technologies Limited (BTTG)
UL INTERNATIONAL (UK) LTD
INSPEC International Ltd.
CCQS UK LTD
ITS Testing Services (UK) Ltd
West Yorkshire Materials Testing Service
(West Yorkshire Joint Services)
SIRA CERTIFICATION SERVICE

25 March 2020

I am writing to ask for your assistance in the fight against Covid-19. As a Notified Body appointed under Article 28 of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment, you have an important role in the conformity assessment of equipment that is vital to combating the current outbreak.

As you may be aware, a Recommendation ([EU 2020/403](#)) from the European Commission was published in the Official Journal on 16 March 2020 (dated 13 March 2020), on conformity assessment and market surveillance procedures within the context of the COVID-19 threat (you can read the text [here](#)). The Recommendation covers Personal Protective Equipment (PPE) and medical devices. It is intended to ensure disruptions to the global supply chain are minimised while continuing to protect health and safety. I can confirm that this Recommendation applies to the UK and to UK Notified Bodies during the Transition Period. Paragraphs 1-4 of the Recommendation are of particular relevance to Notified Bodies.

This letter sets out the steps we are taking and UK Government's response to the Recommendation in relation to PPE, in light of the importance we place on encouraging new manufacturers to produce PPE and enter the market, and in recognition of the need to source PPE that has not been manufactured for the EU or UK market.

In line with paragraph 2 of the Recommendation, the Government **urges all relevant Notified Bodies to prioritise the conformity assessment of all newly submitted PPE requests by economic operators of PPE necessary for protection in the context of the COVID-19 outbreak over other work, and for this work to be conducted swiftly.**

In line with paragraph 3 of the Recommendation, during this period, where PPE products which are submitted for conformity assessment are following technical solutions other than harmonised standards, Notified Bodies may use the World Health Organisation recommendations on the appropriate selection of PPE (copy attached) as a source of reference for these technical solutions, provided that the level of protection corresponds to the applicable essential health and safety requirements.

If a Notified Body issues a certificate of conformity for a PPE product which relies on a technical solution other than a harmonised standard, then the Notified Body should inform other relevant Notified Bodies, through the UK Notified Bodies Co-ordination Group, and inform the Department for Business, Energy and Industrial Strategy as the Notifying Authority, by emailing Harsha.Patel@beis.gov.uk.

You should also be aware that I am also writing to Market Surveillance Authorities to ask them to prioritise checks on PPE necessary for protection relevant to the Covid-19 outbreak. The Recommendation provides that where PPE meets the essential health and safety requirements even though the conformity assessment procedures have not been fully finalised (for example CE marking has not been affixed), MSAs may allow the products to be made available on the market for a limited period of time whilst the necessary procedures are being completed.

In addition, HSE are urgently considering whether masks approved for markets outside the UK/EU will meet essential safety requirements. Therefore, these could be placed on the UK market before conformity assessment or CE marking is completed for a temporary period, in line with the procedure outlined above.

We are currently considering what further steps can be taken to speed up supply of necessary PPE and will be in touch with you again regarding any further measures.

You may also be interested to know that CEN and CENELEC have agreed to immediately make publicly available a number of European standards for certain medical devices and personal protective equipment with immediate effect. This action will help companies willing to manufacture these items to swiftly start production and place products on the market more easily. The 11 standards developed by CEN and 3 additional ones developed jointly with ISO cover common filtering masks, medical gloves and protective clothing.

I would be grateful if you could make your clients aware of these changes and about the free public availability of the European standards (press notice [here](#)). Thank you for your assistance.

I am also copying this letter to HSE, the British Safety Industry Federation and to the Secretary of the PPE Notified Bodies Coordination Group.

Yours sincerely,



Sarah Smith
Deputy Chief Executive
Office for Product Safety and Standards