
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made by the Scottish Ministers in exercise of the powers conferred by paragraph 1 of schedule 19 of the Coronavirus Act 2020. The Regulations are made in order to implement temporary arrangements to facilitate the production and supply of PPE necessary for use during the COVID-19 crisis. These arrangements are similar to the proposals in the European Commission's Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.

Regulation 2 permits PPE to be placed on the market while it is undergoing conformity assessment procedures but before these have been completed and before any conformity marking has been affixed.

Regulation 3 permits PPE to be procured without undergoing conformity assessment procedures and without any conformity marking being affixed but this PPE must only be made available to healthcare workers and other frontline workers.

In both cases, the PPE must have been assessed by the HSE and found to be compliant with the relevant elements of the essential health and safety requirements in Annex 2 of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council [Directive 89/686/EEC](#) (as amended and retained in UK law). Where the conditions are met, the obligations in Regulation 2016/425 will be treated as satisfied for the purposes of the Personal Protective Equipment (Enforcement) Regulations 2018 and in respect of PPE for healthcare workers and other frontline workers, the market surveillance authority will not require the non-compliance to be brought to an end. This is solely in cases where the conformity assessment procedure has not been completed and the conformity mark has not been affixed due to reliance on regulation 2 or 3 of these Regulations.

No Business and Regulatory Impact Assessment has been prepared in relation to these Regulations as no significant impact upon business, charities or voluntary bodies is foreseen.