
EXPLANATORY NOTE

(This note is not part of the Regulations)

The Regulations are made under section 45C of the Public Health (Control of Disease) Act 1984 implementing 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 ((OJ L 79I, 16.3.20 p. 1-5), but the arrangements in these Regulations are specific to England, may only be relied on if the HSE has authorised it by a specified date and come into force on IP completion day.

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 2016/425/EU of the European Parliament and of the Council of 9 March 2016 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 ([S.I. 2018/390](#)) 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.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.