

# Compliance concerns?

## We've got you covered



As you know, there was a revision to PPE Regulations (UE) 2016/425, which came into effect last April. Personal Protective Equipment (PPE) legislation was revised by the UK National Standards body BSI, who issued a directive to replace the PPE 89/686/EEC regulation, which was repealed with effect from 21st April, 2018. The regulation was replaced by the new (EU) 2016/425 regulation, with the key amendments as follows:

PPE CATEGORY	ACTIVITY	OLD PPE DIRECTIVE 89/686/EEC	NEW PPE REGULATION (EU) 2016/425
Category I Simple PPE	Placing product on to the market	Manufacturers self declaration	Module A (Annex IV) Manufacturers self declaration
Category II Intermediate PPE and Category III Complex PPE	Initial product approval	Article 10 EC Type Examination	Module B (annex IV) EU Type Examination plus Module C (Annex VI)
Category III Complex PPE only	On-going surveillance through testing	Article 11A	Module C2 (Annex VII)
OR			
Category III Complex PPE only	On-going surveillance through factory auditing	Article 11B	Module D (Annex VIII)

### Key dates for the new regulations to come into effect:

- PPE Directive 89/686/EEC is repealed with effect from 21st April 2018
- This PPE Regulation (EU) 2016/425 shall apply from 21st April 2018
- Between April 2018 and April 2019 manufacturers can supply products to both the Directive and Regulation. After April 2019 only products compliant with the Regulation can be placed on the market
- EC type-examination certificates issued under Directive 89/686/EEC shall remain valid until 21st April 2023 unless they expire before that date for products in the supply chain

### Here's what you need to do

Firstly, SMI confirms that all of our PPE conforms fully to the PPE Regulation (EU) 2016/425. As a result, our customers can rest assured that every item purchased from us will be compliant, and there is no need to revise your approach or purchasing, as SMI will take care of the compliance on your behalf.

### How will it affect you?

Customers will only be able to purchase PPE items which are CE marked 89/686/EEC until the 21st April 2019. Items with an EC type-examination certificate will only be available up until 21st April, 2023 and only if the standard has not changed – the certificate does not expire before that date, and no changes have been made to the products safety features.

Items with a current EC-type examination certificate can be purchased until 21st April 2023 and then only if they comply with the regulations and come with an EU declaration of conformity. SMI will ensure that we are vigilant in amending our product suite as required to ensure that our customers are only every selecting items which are fully compliant with the new regulations.

### What will SMI do to ensure compliance for our customers?

We have been monitoring the new regulations since before they entered legislation, to prepare for the amended approach and adapt our product suite to ensure full conformity from day one. As a result, we confirm that all of our PPE products will maintain compliance, and we will be transparent about:

- Providing Declarations of Conformity for affected items
- Evidencing our stringent compliance with ongoing sample testing to ensure standards are being maintained
- Evidence that our quality assurance processes at the factory where items are manufactured are audited, compliant, and have a clear and accessible audit trail to prove that this is the case, for every item which we provide for you
- Be proactive in monitoring upcoming amendments to legislation and regulatory best practice for our industry, adjusting our approach accordingly
- Communicate clearly so that our customers can be confident in our compliance.

As a result, our customers may simply continue to purchase their PPE from us, safe in the knowledge that we have covered or exceeded all requirements for your chosen products, and will provide all required evidence to validate this, for every product which we provide.

If you have any queries or questions relating to the new PPE regulations, please do not hesitate to get in touch with one of our team to enable us to assist you. In the meantime, there is a comprehensive guide provided on the PPE regulation amendments, and the specific items of PPE which the new laws relate to, [here](#).