

PPE REGULATION (EU) 2016/425

As of April 21st 2018 the new PPE Regulation (EU) 2016/425 came into force and replaced the PPE Directive 89/686/EEC. This leaflet provides a brief overview of the key changes and a time line of when you can expect to see these taking effect.

What are the main changes?

- Bespoke items of PPE are now included in the directive
- An EU Declaration of Conformity must be made available with every item of PPE or a link provided to where it can be obtained
- Manufacturers are required to put their name and full address on the item of PPE or, where that is not possible, on its packaging or in a document accompanying the PPE, and also within the EU DOC
- The responsibilities of both manufacturers and importers are clearly outlined
- A copy of the product risk assessment must be included with the technical file submitted for certification
- An EU examination certificate will be issued with a compulsory five year validity if there has been no change in design or the manufacture of the product since its last EC type examination, then the current certificate is valid and manufacturers will only be required to re-certify products up to 12 months before the expiry date of the certificate
- All products currently certified to the directive having been tested to the latest standards can remain on the market until 21st April 2023 or until the expiry date of the certificate. If the products have been tested to a standard that has been revised or withdrawn, the product certification is no longer valid and the products must be recertified to the 2016/425 regulation by 21st April 2019
- Gloves must be tested to the new EN388:2016 standard by 21st April 2019 to be able to be certified to the new regulation

Time line of key dates for regulation transition

Between April 2018 and April 2019 manufacturers can supply products within the EU certified to both the Directive and the Regulation. From April 21st 2019 new products can only be placed on the market certified to the new Regulation.

Regulation adopted 12 Feb 2016	Regulation listed		Regulation Applies		All EC-Type certificates to PPE Directive invalid
April 2016			April 2018	April 2019	2023
Regulation published	Two year transition		Gloves certified to new PPE Regulation		
	EC Certificates can be issued to old PPE Directive				
EC-Type Certificates to old PPE Directive remain valid until 2023 unless they expire before that date					

The new directive applies not just to manufacturers, but importers, distributors and everyone involved in the supply of PPE. Manufacturers need to ensure all product certification is kept up to date and distributors and resellers need to ensure the product they are placing on the market is fully compliant.

