

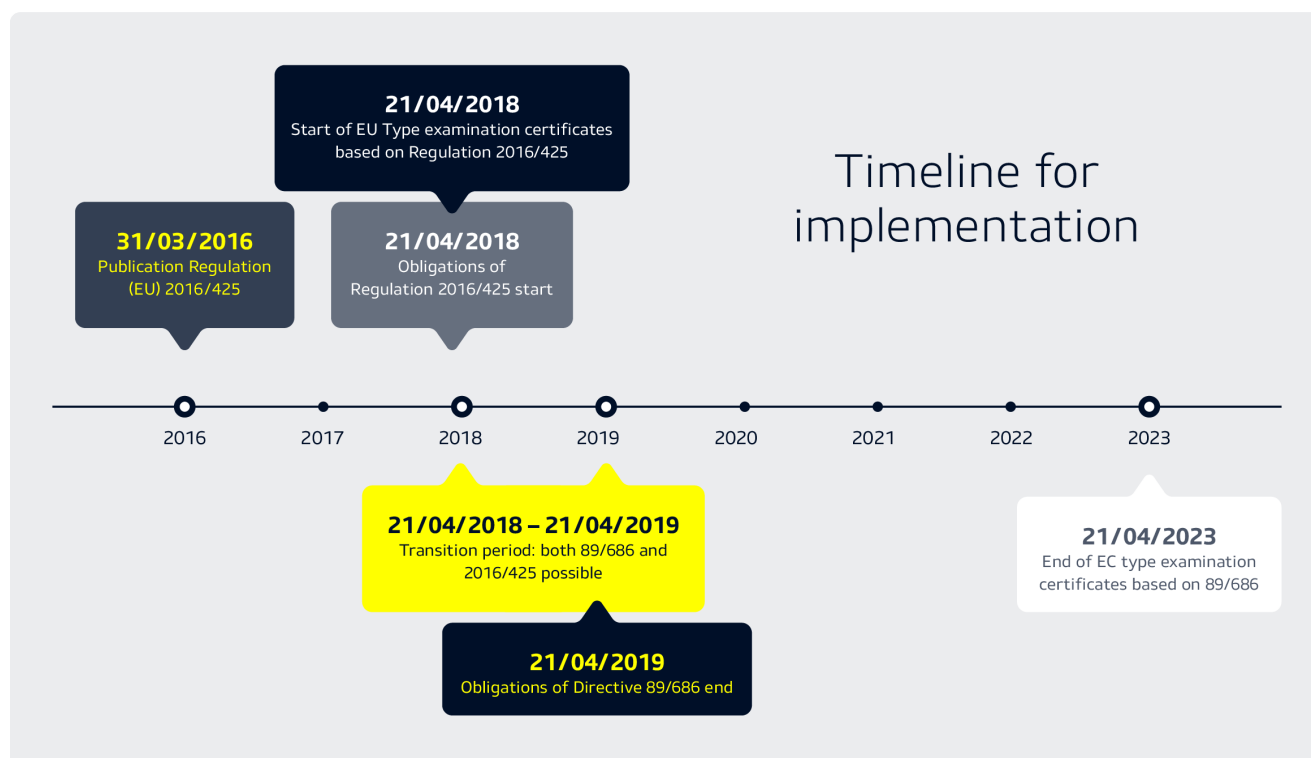
Scandia Gear Europe | Guide to the Revised PPE Regulation (EU) 2016/425

Personal Protective Equipment (PPE) Directive 89/686/EEC was ratified in 1989 and, apart from some minor revisions, has remained largely unchanged.

Why is this PPE regulation changing?

To reflect current technologies and processes for developing PPE and bringing it to market, the directive required updating. The new PPE Regulation (EU) 2016/425 adopts the revisions made to other directives in recent years and re-implements the directive as a regulation. This means that the new regulation will not have to be altered in accordance with each member state's national laws; the new regulation is a binding legislative act and must be applied in its entirety across the EU.

The text of the new regulation was adopted 12 February 2016, published 31 March 2016, was listed in the Official Journal of the European Union 21 April 2016, and will take effect 21 April 2018.



The main changes in Regulation (EU) 2016/425 are:

- Clothing with reflective or fluorescent elements, specifically those included for decoration or as a design element, and intended for private use is not considered PPE and is not subject to this regulation.
- Products that protect against moderate atmospheric conditions (e.g., rain, humidity, etc.) and are intended for private use (e.g., dishwashing gloves) are not covered by this regulation.
- PPE that provides protection against heat (e.g., oven mitts) and is intended for private use is now covered by this regulation and must conform to the safety standards applicable to products designed for professional use.
- Products that provide protection against the following hazards have been reclassified as category III PPE (formerly category II):
 - Drowning (e.g., life jackets)
 - Cuts and abrasions from handheld chainsaws
 - High-pressure jet cutting
 - Blades and bullets
 - Harmful noise

Note: the categorisation of the above-mentioned items is subject to ongoing review.
- A Declaration of Conformity (DOC) must be issued for each item of PPE. The DOC may be provided to wearers via a web link.
- A five (5)-year validity period for EU Type Certificates. Prior to this change, validity periods were indefinite.
- Conformance procedures and responsibilities for importers and distributors.
- Specific instructions pertaining to the design and creation of custom PPE.

Obligations for manufacturers, importers, and distributors

- Manufacturers, their service providers, and their respective supply chains are legally obligated to comply with the Regulation.
- Importers, distributors, and manufacturers must ensure that their PPE complies with the Regulation's requirements.
- Importers must ensure that their PPE is accompanied by product information for the user and/or wearer. Manufacturers must provide, with each item of PPE, either a hardcopy of the item's EU DOC or a web link to it.
- In their technical documentation, manufacturers must include a description of their internal quality control procedures.

Validity periods

- EU Type Certificates are valid for five (5) years
- In the following instances, manufacturers are responsible for asking the notified body to review the EU Type Certificate:
 - In case of modifications
 - In case of a change in standards, essential health and safety requirements (EHSR), or the latest "state-of-the-art" (i.e., technical developments)
 - Prior to the certificate's date of expiration
(To allow the notified body time to complete its tasks, manufacturers may submit their applications 12 months prior to the certificate's expiration and must submit their applications at least six (6) months prior to the certificate's expiration.)

Category definitions and changes by category

Category I – Simple PPE; exclusively for minimal risks

PPE Directive 89/686/EEC

- Superficial mechanical action
- Minor impacts and lesions
- Contact with hot surfaces <50°C
- Atmospheric conditions that are not exceptional
- Sunlight (sunglasses)

New PPE Regulation (EU) 2016/425

- Superficial mechanical injury
- Contact with hot surfaces < 50°C
- Atmospheric conditions that are not of an extreme nature
- Exposure to sunlight (not observing the sun)
- Contact with cleaning materials, weak action, and prolonged contact with water

Category II – Intermediate PPE; risks other than those listed in Categories I and III

PPE Directive 89/686/EEC

Category II includes risks other than those listed in Categories I and III

New PPE Regulation (EU) 2016/425

Category II includes risks other than those listed in Categories I and III

Category III – Complex PPE; includes risks that may cause very serious consequences such as death or irreversible damage to health

PPE Directive 89/686/EEC

- Filtering respiratory devices
- Respiratory protective devices
- PPE for chemical attack or ionizing radiation
- High-temp environments > 100°C
- Low-temp environments < - 50°C
- Fall arrest
- PPE against electrical risks

New PPE Regulation (EU) 2016/425

- Substances and mixtures hazardous to health
- Oxygen deficient atmospheres
- Harmful biological agents
- Ionising radiation
- High-air temp environments > 100°C
- Low-air temp environments < - 50°C
- Fall from a height
- Electric shock and live working
- Drowning
- Cuts by hand-held chain-saws
- High-pressure jets
- Bullet wounds or knife stabs
- Harmful noise

Changes from articles to modules for PPE categories in PPE Regulation 2016/425

PPE Category	Activity	PPE Directive 89/686/EEC	New Regulation 2016/425
Category I – Simple PPE	Placing product on the market	Self-certification	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 V) EU Type Examination Module C (Annex VI) Conformity to type based on internal quality control
Category III – Complex PPE only	Ongoing surveillance through testing	Article 11A	Module C2 (Annex VII)
	or		
	Ongoing surveillance through factory auditing	Article 11B	Module D (Annex VIII)

Unless they expire prior to the Directive's effective end date, EC Type examination certificates issued under Directive 89/686/EEC remain valid until 21 April 2023.

Recommendations to Users/Wearers:

- Ensure that PPE is purchased from a trusted supplier.
- Health and safety managers and purchasers of PPE must ensure that PPE originates from manufacturers who comply with the conditions stated in the new PPE regulations. To confirm compliance, request a DOC for each item in your inventory of workwear and PPE.

Scandia Gear, Workforces, and PPE Regulation 2016/425

Our mission is as it has always been: eliminating LTIs for seaborne workforces.

Chief among our priorities in coordinating our compliance with the upcoming **repeal of Directive 89/686/EEC**, scheduled for April 21st, and in preparing for the enactment of Regulation (EU) 2016/425, is updating our clients and their workforces on our what we are doing.

To confirm: **the new PPE regulation, EU 2016/425**, revises risk criteria and, with that, products' risk categorisations. Scandia Gear is heavily invested in ensuring that our products' CE certifications are comprehensive and up-to-date. Given this, we will be fully compliant with the new legislation in advance of **April 2023**.

To us, product and regulatory information are critical to workplace safety. In accordance with (EU) 2016/425, we will begin providing, through our website, a downloadable DOC for each product in our inventory. We have also put together the above-mentioned timeline, detailing the developments that led to the new PPE regulations and the milestones that will lead to the eventual expiration of Directive 89/686/EEC in 2023.

Look forward to updates about what we are doing and what you can expect from us in response to these changes.