The New PPE Regulation (EU) 2016/425

• The new regulation updates and strengthens the rules governing the placement of Personal Protective Equipment (PPE) on the market in the European Union (EU).
• Replaces the old Personal Protective Equipment (PPE) Directive (89/686/EEC)
• Is a binding legislative act

The Personal Protective Equipment (PPE) at Work Regulations 1992, which govern the employer on the suitability, provision, maintenance, instruction and use of PPE still stand.
The only change is that once they required employers to select appropriate PPE in line with the Personal Protective Equipment Regulations 2002, they now the require employers to choose appropriate PPE which has been CE marked in accordance with The PPE Regulation.

Obligations of Economic Operators

An Economic Operator can be defined as the manufacturer, the representative, the importer and the distributor.
All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only PPE which is in conformity with this Regulation.
This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

What must manufacturers do?

• Provide the EU Declaration of Conformity with the PPEor provide with the user instructions an internet address at which the EU Declaration of Conformity can be downloaded.
• Ensure that procedures are in place for series production to remain in conformity with the PPE Regulation.
• Draw up all technical documentation referred to in Annex III.
• Carry out a product risk assessment and shall envisage not only the intended use but also the reasonably foreseeable uses (Annex III).
• Retain all technical documentation for 10 years after the PPE has been placed on the market.
• Carry out sample testing of PPE made available in the market, keep a register of complaints and keep distributors informed of such monitoring.
• Mark the product or packaging with their name or registered trade name or mark and a single point postal address.
• Inform the competent authorities when they become aware of PPE that presents a risk.
• Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity shall immediately take corrective measures necessary to bring it into conformity, to withdraw it or to recall as appropriate.
• Supply manufacturer instructions with the smallest individual sales unit in a language easily understood by the end user and market surveillance authority.

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What must importers do?

• Before placing PPE on the market importers shall ensure the conformity assessment procedure has been carried out by the manufacturer.
• Ensure the manufacturer has completed all technical documentation referred to in Annex III.
• Retain the Declaration of Conformity for 10 years after the PPE has been placed on the market and ensure the technical documentation is available to the authorities on request.
• Ensure instructions for use (IfU) to be supplied with the smallest individual sales unit in a language easily understood by the end user and market surveillance authority.
• Carry out sample testing where appropriate of PPE made available in the market, keep a register of complaints and keep distributors informed of such monitoring unless they have deemed it not appropriate.
• Mark the product or packaging with their registered trade name or mark and a single point postal address.
• Inform the competent authorities when they become aware of PPE that presents a risk.
• Importers who consider or have reason to believe that PPE which they have made available on the market is not in conformity shall make sure that the corrective measure necessary to bring it into conformity, to withdraw it or to recall it are taken.
• Be prepared to participate actively in market surveillance tasks.

What must distributors do?

• Act with due care when placing product on the market.
• Before placing PPE on the market, Distributors shall verify that it bears the CE Marking, is accompanied by the required documents and the instructions for use and all required information.
• Before placing PPE on the market, distributors must ensure the conformity assessment procedure has been carried out by the manufacturer.
• Inform the competent authorities when they become aware of PPE that presents a risk.
• Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring it into conformity, to withdraw it or to recall it are taken.
• Be prepared to participate actively in market surveillance tasks.

PPE Categories explained

Each Category of PPE must comply with clearly defined conformity assessment modules prior to being placed on the market. The categories include:

Category 1 - Simple PPE

PPE in this category is designed to protect people from minimal risks. These include:
• Superficial mechanical injury
• Contact with cleaning materials of weak action or prolonged contact with water
• Contact with hot surfaces not exceeding 50°C
• Damage to the eyes due to exposure to sunlight (other than during observation of the sun)
• Atmospheric conditions that are not of an extreme nature.

Manufacturers of simple design PPE are allowed to assess the level of protection via internal production control and declare conformity by means of a Declaration of Conformity, without verification by a notified body.

Category 2 - Intermediate PPE

This category covers risks other than those defined by neither Category I nor Category 3.

Category 2 PPE is subject to an EU type examination by a notified body, following which the manufacturer will need to supply the customer with a Declaration of Conformity.
The manufacturer must also have an internal production control system to ensure the product continues to conform.

Category 3 - Complex PPE

PPE that comes under Category 3 is designed to protect people from risks that may cause very serious consequences such as death or irreversible damage to health.

Category 3 relates to the following:

• Substances and mixtures which are hazardous to health
• Atmospheres with oxygen deficiency
• Ionising radiation
• High-temperature environments the effects of which are comparable to those of an air temperature of at least 100°C
• Low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less
• Falling from a height
• Electric shock and live working

Some types of protection have moved from Category II (Intermediate) to Category III (Complex) The Regulation now ensures that life-changing occupational illnesses receive the attention they deserve.

The following risks have now been added to Category III
- Harmful biological agents
- Drowning
- Cuts by hand-held chain-saws
- High-pressure jets
- Bullet wounds or knife stabs
- Harmful noise

All types of Hearing Protection against harmful noise have been re-classified to Category - III (Complex), which is designed to protect against very serious risk, where the hazard is not immediately obvious. The effects of hearing loss is now recognised as being severely damaging to a person's quality of life.

Manufacturers of Category III PPE are subject to an EU type examination by a notified body and to one of the two quality assurance procedures as described in Article 19 of the PPE Regulation.

The responsibility for implementing the changes of the new Regulation in relation to items reclassified as Category III products rests with the manufacturer. They must agree with a notified body the ongoing quality control conformity assessment procedure of the protective equipment
a) during production (i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII; or b) the physical testing of the final products. (ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

Upon completion, the manufacturer must compile a Declaration of Conformity. This will be issued in accordance with the Regulation from April 2018 and should contain the detail s of the notified body who has issued the ongoing conformity module D or C2 certification.

As detailed below in an extract from the regulation.
Annex IX - Clause 8. Where applicable, the PPE is subject to the conformity assessment procedure … (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) … under surveillance of the notified body … (name, number).
Upon completion, the manufacturer must compile a Declaration of Conformity

If you are buying PPE that has been reclassified this is what you need to do:
Only acquire reclassified PPE products from suppliers that comply with the conditions of the new PPE regulation.
Check the certification is to the latest version of the standard and ensure that it meets the new Regulation requirements.
Check the Declaration of Conformity for details of the notified body. Check that it details the notified body who has issued the ongoing conformity module D or C2 certification.
Look for updated marking on the product, packaging and user instructions. Under or beside the CE mark, there needs to be a notified body number which is generally four digits and identifies the notified body who conduct the ongoing conformity assessment.
Identification of notified body code numbers can be found at http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main.

The ongoing conformity assessment procedure can be completed by another certification body and you may wish to request a copy of this certification.

Where it is not possible to display the CE mark on the product such as on small ear plugs, the marking may be displayed on the packaging and in the user instructions.

The user instructions should also include the Declaration of Conformity or an internet address where the complete Declaration of Conformity can be found.

The manufacturer’s address or single point of contact also needs to be visible on the product or where this is not possible on the packaging.