

## What is The PPE Directive, and why is it changing?

The PPE Directive 89/686/EEC covers the manufacture and marketing of Personal Protective Equipment. It defines legal obligations to ensure that PPE on the European market provides the highest level of protection against hazards. The CE marking affixed to PPE provides evidence of this protection.

### What is changing?

As of 21 April 2018, Directive 89/686/EEC will be repealed by the new Regulation (EU) 2016/425 of the European Parliament.

The new PPE Regulation is aligned to the New Legislative Framework policy. In addition, it slightly modifies the scope and the risk categorisation of products. It also clarifies the documentary obligations of economic operators (Distributors, Importers, Manufacturers).

#### **The main changes are:**

- \* Moving hearing protection from Category II to Category III PPE.
- \* Moving life jackets from Category II to Category III PPE.
- \* Issuing a Declaration of Conformity with each PPE or at least a link to where it can be obtained.
- \* A compulsory maximum five-year certificate validity.
- \* Responsibilities outlined for importers and distributors.
- \* Bespoke PPE covered in the Regulation.

#### **Other smaller changes include:**

- \* CAT I (Minimal risk) items are now covered under Module A for self-certification.
- \* CAT II (Intermediate) items are now covered under Module B and will be issued an EU type certificate from notified bodies.
- \* CAT III (Complex) items are now covered under:
  - Module C2 (used to be Article 11A) which is ongoing surveillance through testing.
  - Module D (used to be Article 11B) which is ongoing surveillance through factory auditing.

#### **Timescale Breakdown:**

- \* All of the old EC type certification shall expire April 2023 unless an earlier expiry date exists.
- \* All technical information MUST be available for 10 years, even if the item is discontinued.
- \* The manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU Type-Examination certificate.

## What does this mean to PPE Manufacturers in the supply chain behind MTS?

Our preferred supply chain have been making many of the changes ahead of the deadlines.

**Moving hearing protection from Category II to Category III PPE:**

Will be done before expiry deadline 21/04/2019.

**Moving life jackets from Category II to Category III PPE:**

Does not apply to MTS or our supply chain.

**Issuing a Declaration of Conformity with each PPE or at least a link to where it can be obtained:**

All Declarations, User sheets and care labels have been available on request for some time. All User sheets are being re-designed with the intention to include an online link to the Declarations.

**A compulsory maximum five-year certificate validity:**

More Than Safety have ensured our supply chain either already adhere to this or are on target to do so before the deadline.

**Bespoke PPE covered in the Regulation:**

Does not apply to MTS.

## What does this mean to MTS?

- \* When making PPE available on the market, all involved shall act with due care in relation to the requirements of this Regulation.
- \* Before making PPE available on the market, we shall verify that it bears the CE marking and is accompanied by the required instructions in a language which can be understood by end-users in the country which PPE is to be made available.
- \* We shall ensure that, while the PPE is under our responsibility, storage or transport conditions do not jeopardise its conformity.
- \* Where we consider or have reason to believe that PPE which we have made available on the market is not in conformity with this Regulation we shall withdraw it or recall it.
- \* We shall electronically store all documentation about the products for 10 years minimum even if a product is discontinued.

## What does this mean for you, our customers?

You can continue to trust MTS as your responsible PPE supply partner, assured that our practices are fully compliant with the new regulations.