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Certification to the PPE Regulation – Transition from PPE Directive to Regulation

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When does the new PPE Regulation (EU) 2016/425 apply?

The Regulation text was adopted on the 12th February 2016 and published on the 31 March 2016.

It was listed in the Official Journal on the 21st April 2016. This started the two-year transition period for Member States and Notified Bodies to prepare for the introduction of the new Regulation.

The PPE Regulation comes in to force on the **21st April 2018** repealing the current PPE Directive (89/686/EEC).

What are the main changes in the new PPE Regulation (EU) 2016/425?

There are a number of changes including:

- New legislation now a Regulation, which is directly applicable and a binding legal force throughout every Member State (opposed to a Directive; where each Member State is free to decide how to transpose directives into national laws).
- Scope to include PPE designed and manufactured for private use to protect against heat (domestic oven gloves).
- Moving hearing protection and ***lifejackets (level 100, 150 and 275) from Category II to Category III PPE***.
- Manufacturer must issue 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 (N.B. FTH already apply this as of 2009 as per BSIF agreement for UK NB's).
- Responsibilities outlined for importers and distributors (to be same as manufacturer).
- Bespoke PPE (made to measure PPE) covered in the Regulation.
- EC Type examination certificates changed to EU Type examination certificates.
- New Modules for route of conformity (similar to MED Directive) Module B for EU Type examination and Module C2/Module D for conformity to type surveillance of Category III products.
- Additional technical documentation requirements to be supplied by the Manufacturer as part of the technical file.

What are the transition timelines of the PPE Regulation?

The PPE Regulation (EU)2016/425 comes in to force on the **21st April 2018** repealing the current PPE Directive (89/686/EEC).

Manufacturers have until the **21st April 2019** (one year) to update existing Article 10, EC Type examination certificates against the PPE Directive, to EU Type examination certificates against the PPE Regulation.

Manufacturers can no longer place product on the market using an Article 10 EC Type examination certificate against the PPE Directive after 20th April 2019.

For products moving to Category III (which includes all lifejackets level 100, 150 and 275), manufacturers must have new Module C2 or Module D certification in place by **21st April 2019**.

Products which are already placed on the market remain valid with the existing EC Type examination certificate of approval until **21st April 2023**. (This applies to individual product not model type!)

For products certified using now withdrawn standards these must be updated to current state of the art (e.g. EN 39X standards replaced with EN ISO 12402).

What does this mean for Manufacturers?

All manufacturers with current Article 10 EC Type examination certificates against the PPE Directive must update to new EU Type examination certificates against the PPE Regulation by **21st April 2019**. This will apply for **ALL** product types that have previously been certificated against the PPE Directive.

This can be done via a simplified procedure if there have been no changes to the product and no changes to the state of the art. The manufacturer must submit the additional information required by the PPE Regulation to update the existing technical file, marked information and user information (where relevant). On satisfactory receipt of all updated technical documentation FNB will issue a new EU type certificate. ***Please note that any EU type examination certificate issued against the PPE Regulation prior to the 21st April 2018 will be post-dated and will not become valid until 21st April 2018.***

All Category III products (including deck safety harnesses, safety lines and lifejackets level 100, 150 and 275) must be in compliance with the new Module C2/ Module D conformity assessment by **21st April 2019**.

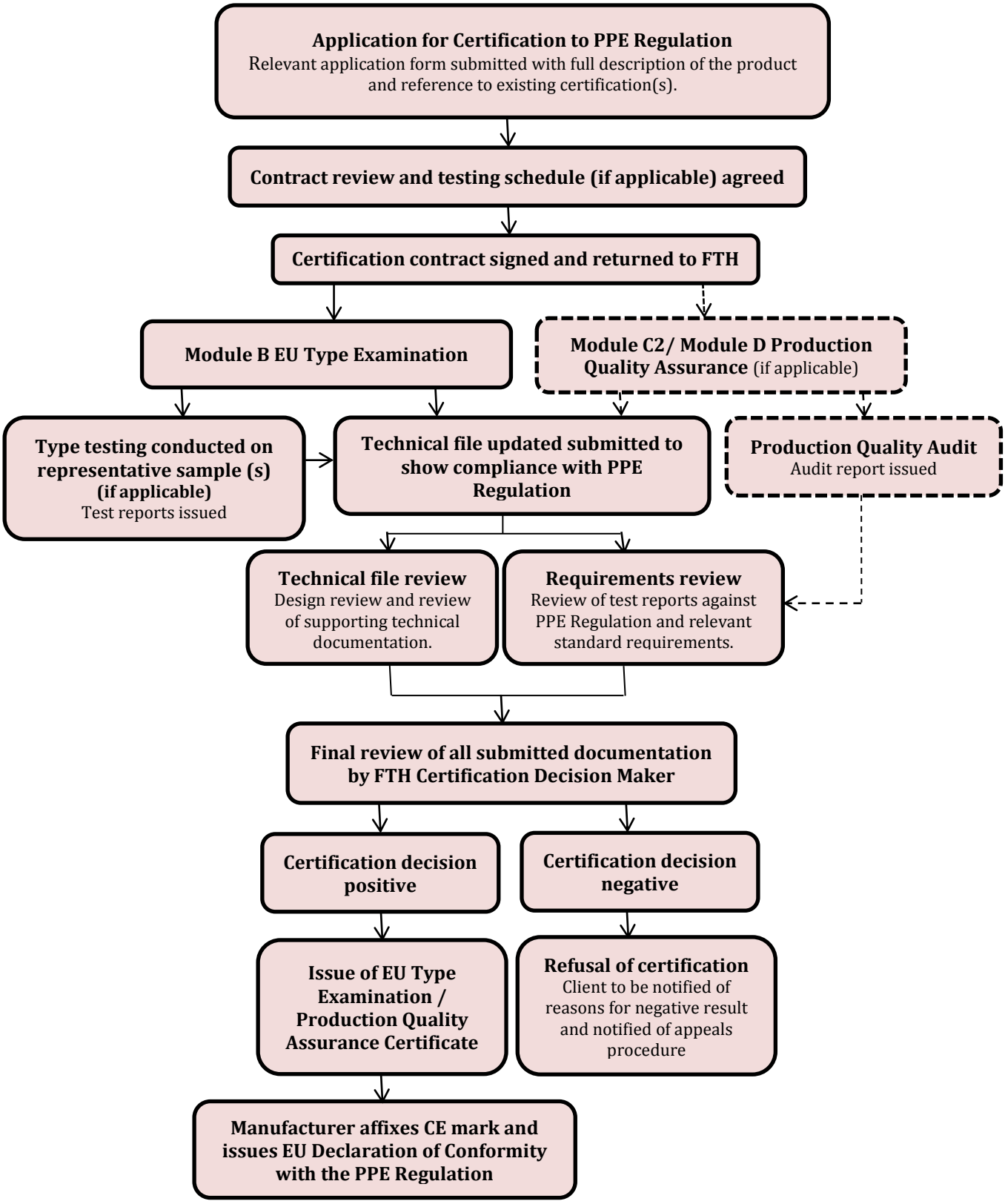
Any products approved to withdrawn standards e.g. EN39X approved products, will be eliminated from the market unless they are retested and approved to the latest standard.

Additional technical documentation requirements of the PPE Regulation

FNB will be asking for the following additional information to be supplied as part of the technical file documentation to show compliance with the requirements for the PPE Regulation (see Annex III of the PPE Regulation for full details):

- The technical file must include an assessment of the risks against which the PPE is intended to protect, in the form of a risk matrix or statement including a list of the essential health and safety requirements that are applicable to the PPE and references of the harmonised standards applied (where applicable).
  Note: The PPE Regulation also requires the date of the standard to be included in the user instructions.
- Manufacturer's instructions and information must include reference to the PPE Regulation EU/2016/425 (see Annex II, 1.4) and the internet address where the EU declaration of conformity can be accessed.
- Declaration of mark of conformity (CE mark) - Provide a statement of compliance in accordance with Article 17.
- An example of Declaration of Conformity (D of C) that is to be supplied with the product (this is to be checked against PPE Regulation requirements in Annex IX).
- A statement of how the D of C can be accessed by the relevant authorities, i.e. website link.
- An additional statement to be included to state that all Technical documentation and D of C's will be kept for at least 10 years.
- Declaration of innocuousness should cover the requirements of Annex II, 1.2.

FNB Procedure for transition to the PPE Regulation (EU) 2016/425



Module B (Annex V) EU Type Examination

This procedure is equivalent to the existing third party Article 10 EC Type Examination under the current PPE Directive. The only difference being that EU Type Examination certificates are issued and the validity of the certificate cannot exceed 5 years. (FNB have applied a maximum 5 year validity to EC Type Examination certificates since 2009 and so there will be no change to this renewal procedure). Full information can be found in Annex V of the PPE Regulation.

EU Declaration of Production Conformity

The EU declaration of conformity is the procedure whereby the manufacturer or his authorized representative draws up a declaration (see Article 15 and Annex IX of PPE Regulation (EU) 2016/425) certifying that the PPE placed on the market are in conformity with the provisions of the Regulation and affixes the CE mark to each PPE.

The following information must be included as part of the EU declaration of conformity:

1. PPE (product, type, batch or serial number).

2. Name and address of the manufacturer and, where applicable, his authorised representative.

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included).

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: XX.

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared.

7. Where applicable, the notified body (name and number) who performed the EU type-examination (Module B) and issued the EU type-examination certificate (reference to that certificate).

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).

9. Additional information:
Signed for and on behalf of: (place and date of issue)
(name, function) (signature)
Note: It is optional for the manufacturer to assign a number to the declaration of conformity.

The CE Mark

The CE marking is the manufacturer's declaration that the product meets the requirements of the PPE Regulation. Once you have satisfied the conformity assessment requirements for CE marking the CE marking must be applied to the product and/or its packaging. The CE Mark must be applied to all applicable products under assessment and applied in accordance with Article 16 and Article 17 of the PPE Regulation.

Rules and conditions for affixing the CE marking under the PPE Regulation:

1. The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE.

2. The CE marking shall be affixed before the PPE is placed on the market.

3. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure set out in Annex VII or VIII. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.

5. The CE marking shall be at least 5 mm high (Requirement of Regulation (EC) No 765/2008, Annex II).

Lifejackets change to Risk Category III

Under the new PPE Regulation Lifejackets have been changed from risk category II to risk category III. This includes lifejackets performance level 100, 150 and 275 (buoyancy aids level 50 are not included). This means that in addition to the third party EU Type examination under Module B the manufacturer must also have comply with one of the conformity assessment modules (either Module C2 or Module D) to be able to affix the mark of conformity and place product on the market. The manufacturer must comply with the additional conformity modules before **21st April 2019**.

Module C2 (Annex VII) Conformity to type based on internal production control plus supervised product checks

Similar to the current Article 11a conformity assessment procedures under the current PPE Directive this requires a manufacturer to have internal production control plus supervised product checks at random intervals to ensure homogeneity of production and conformity of the manufactured PPE. The notified body must carry out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type examination certificate and with the applicable essential health and safety requirements. The product checks must be carried out at least once a year, at random intervals determined by the notified body. The notified body will provide the manufacturer with a test report. The manufacturer shall affix the CE marking and, under the responsibility of the notified body, the notified body's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate. ***Full information can be found in Annex VII of the PPE Regulation.***

Module D (Annex VIII) Conformity to type based on quality assurance of the production process

Similar to the current Article 11b conformity assessment procedures under the current PPE Directive this requires a manufacturer to operate with an approved quality system for production, final product inspection and testing of the PPE concerned to ensure that the PPE is in conformity with the type described in the EU type examination certificate. The notified body shall assess the effectiveness of the quality system at the location of manufacture to determine whether it satisfies the requirements of Module D, 3.2. The result of that assessment will be reported by the notified body. The notified body must carry out periodic audits, at least once per year. The manufacturer shall affix the CE marking and, under the responsibility of the notified body, the notified body's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate. ***Full information can be found in Annex VIII of the PPE Regulation.***

Please contact us if you have any additional questions regarding the transition to the PPE Regulation.