FLEETWOOD TEST HOUSE

FLEETWOOD NOTIFIED BODY

Certification Schemes

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Contents

Fleetwood Test House – Background

Fleetwood Test House (FTH) is part of Blackpool and the Fylde College which is one of the leading educational establishments in the UK offering a number of higher education and further education courses celebrating 125 years as one of the UK's leading further education colleges. Blackpool and the Fylde College have multiple campuses around Blackpool and the Fylde area including Fleetwood Nautical Campus where FTH is based.

Fleetwood Nautical Campus has been involved in nautical education and training since 1890. The Offshore Survival Centre (FOSC) has operated since 1982 specialising in training for the offshore oil and gas industry. The vast experience in training with marine lifesaving equipment was the catalyst for the testing of PPE and this resulted in the beginning of Fleetwood Testing Laboratory (FTL) which was formed in 1988. FTL has now been a UKAS accredited testing laboratory since October 1994.

In 1993 a purpose-built swimming pool was opened at Fleetwood Nautical Campus specifically for water-based training and for the testing of PPE. In 1995 as a result of demand from our customers, FTL applied for appointment as a Notified Body so that we could offer services for both testing and certification of PPE against drowning. Fleetwood Testing Laboratory became Fleetwood Test House, which incorporated both the existing FTL and the new Fleetwood Notified Body (FNB).

To this day Fleetwood Test House prides itself on its integrity and experience in this sector in the field of PPE against drowning and Marine equipment, both as a competent accredited test house and as end users as part of one of the leading offshore training schools in the UK and our impressive facilities offer a comprehensive service for training, testing and certification.

Fleetwood Test House – Certification Schemes

Fleetwood Notified Body (FNB) is appointed as a Notified Body (NB identification number 0514) by the United Kingdom Department for Business, Energy & Industrial Strategy (BEIS) to perform conformity assessments according to the following European Directives:

- Regulation (EU)2016/425 for Personal Protective Equipment (PPE)
- Directive 2014/90/EU for Marine Equipment

Scope of Products:

FTH offers testing* and certification for the following PPE products in accordance with the PPE Regulation (EU) 2016/425:

- Lifejackets
- Buoyancy Aids
- Deck Safety Harnesses and Safety Lines
- Immersion Suits
- Swim Aids
- Diving Wet Suits
- Diving Dry Suits

We also offer testing* and certification for the following Life Saving Appliances in accordance with the Marine Equipment Directive 2014/90/EU:

- Lifejackets
- Immersion Suits
- Thermal Protective Aids
- Lifebuoys

Our notification as a UK Notified Body can be found on the NANDO-website.

***Testing is performed by Fleetwood Testing Laboratory which is an ISO 17025 accredited testing laboratory, accredited by the United Kingdom Accreditation Service (UKAS). UKAS testing laboratory number 1559.**

The PPE Regulation

The PPE Regulation (EU) 2016/425 came into force on the 21st April 2017 and it covers the manufacture and marketing of personal protective equipment (repealing the existing PPE Directive 89/686/EEC).

Note: The PPE Directive can no longer be used to place product on the market as of 21st April 2019).

The PPE Regulation 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.

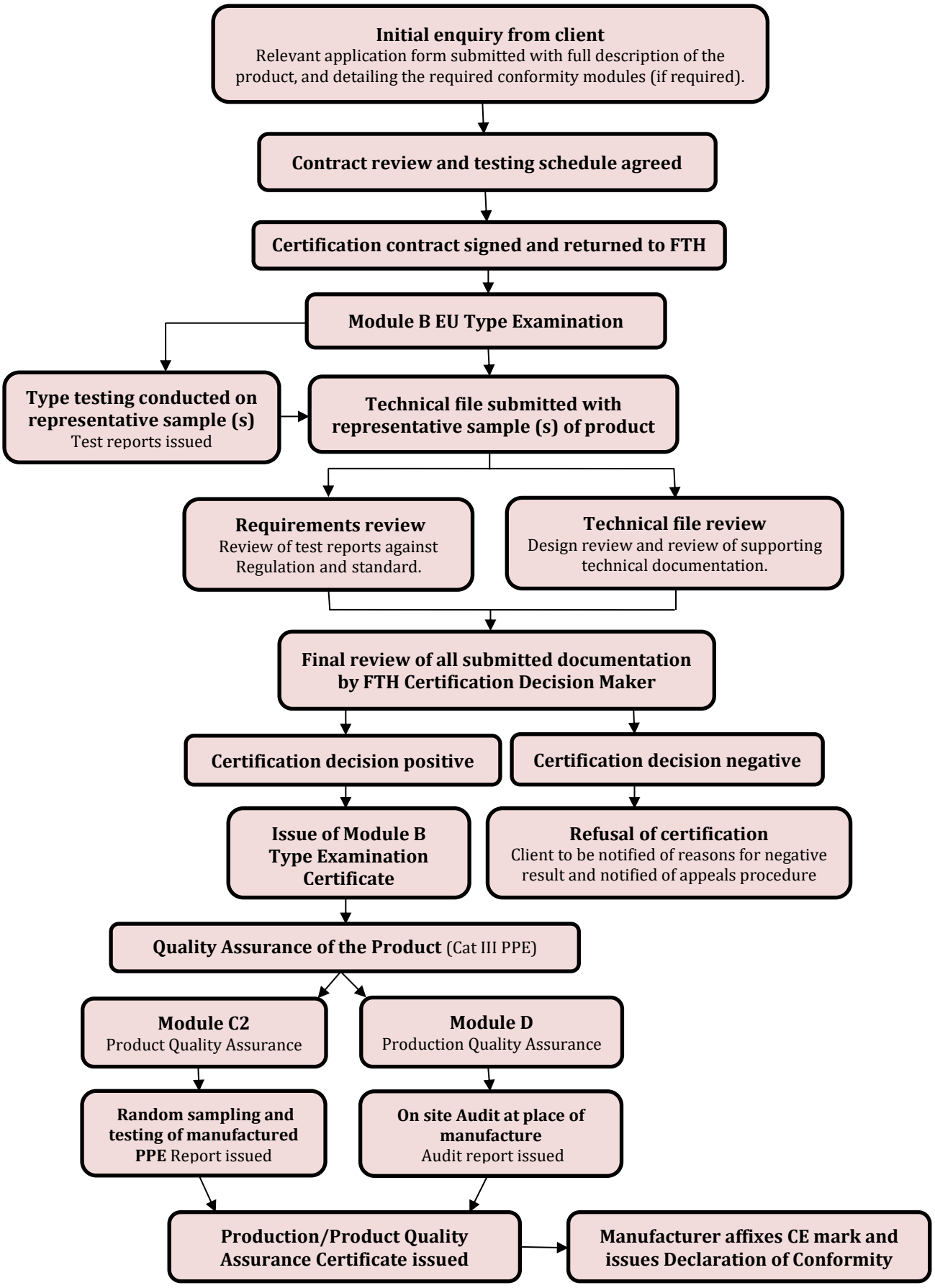
FNB notified body activities cover conformity assessment of category II and III PPE in accordance with the PPE Regulation, including the following:

- Type examination of the product (Module B)
- Checking of PPE manufactured for continued homogeneity (Module C2 or Module D)

The Blue Guide contains guidance on the application of all aspects of the implementation of EU products rules, including conformity assessments. More information can be found at the following European Commission website address:

https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en

Fleetwood Notified Body PPE Certification Process



Product Conformity with the PPE Regulation: EU Type-Examination

Type-examination is the procedure whereby the approved inspection body establishes and certifies that the PPE model in question satisfies the relevant provisions of the PPE Regulation. This involves the following procedures by the Notified Body (NB):

(a) **Examination of the manufacturer's technical file**: The NB shall examine the manufacturer's technical file to establish its suitability with respect to the relevant harmonized standards or, where no such standards are available, the relevant technical specifications covering the essential health and safety requirements (EHSR) of the PPE Regulation.

(b) **Examination of the model:** The NB shall verify that the product has been produced in accordance with the manufacturer's technical file, and will include the necessary type testing to establish conformity of the model with the harmonized standards, or, where no such standards are available, the relevant technical specifications covering the EHSR of the PPE Regulation.

Product Conformity with the PPE Regulation: Production Quality Assurance

Under the PPE Regulation for PPE of complex design (Category III), a manufacturer must take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EU type-approval certificate and with the EHSR requirements of the PPE Regulation. This involves checking of the PPE by the NB by either of the following routes:

- **Module C2. 'Conformity to type based on internal production control plus supervised product checks at random intervals':** The NB takes a random statistical sampling of the PPE. The samples are then examined to confirm that the manufactured PPE is as type-examined and remains in conformity with the standard or specification referenced on the corresponding valid type-examination certificate; or

- **Module D. 'Conformity to type based on quality assurance of the production process':** The notified body shall carry out periodic audits at the manufacturers premises, where the final assembly of PPE is carried out, to make sure that the manufacturer maintains and applies the quality system.

These checks are carried out at intervals of at least once per year and a NB will issue a report to show the conclusions of the inspection and, if required, issue a production quality assurance certificate.

EU Declaration of Production Conformity for PPE

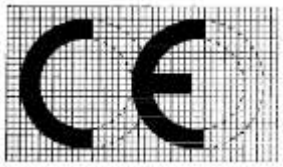
The EU declaration of conformity is the procedure whereby the manufacturer or his authorized representative draws up a declaration (see Annex IX of PPE Regulation (EU) 2016/425) certifying that the PPE placed on the market are in conformity with the provisions of the Regulation and affixes the CE mark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

The 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 17 of the PPE Regulation (EU) 2016/425.

There are specific rules for using the CE marking on a product, as well as rules for the reproduction of the CE marking logo. The following general rules apply:

- The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted because of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE.
- The CE marking shall be affixed before the PPE is placed on the market.
- 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 Module C2 or Module D.
- 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.
- 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.
- The CE conformity marking shall consist of the initials 'CE' taking the following form:



- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale PPE.

The Marine Equipment Directive (MED)

The MED covers the manufacturing of equipment for the marine industry for use in the European Economic area. As of 16 September 2016, Directive 96/89/EC was repealed and replaced with Directive 2014/90/EU.

Directive 2014/90/EU stipulates that marine equipment to be installed on new or existing ships shall be approved to, and bear the "Wheelmark" (mark of conformity); this requires the involvement of a Notified Body approved to assess products covered by the MED.

FNB Notified Body activities in accordance with the MED cover conformity assessment of marine equipment under the category of Life Saving Appliances (LSA), specifically lifejackets, immersion suits, TPA'S and lifebuoys, and includes the following:

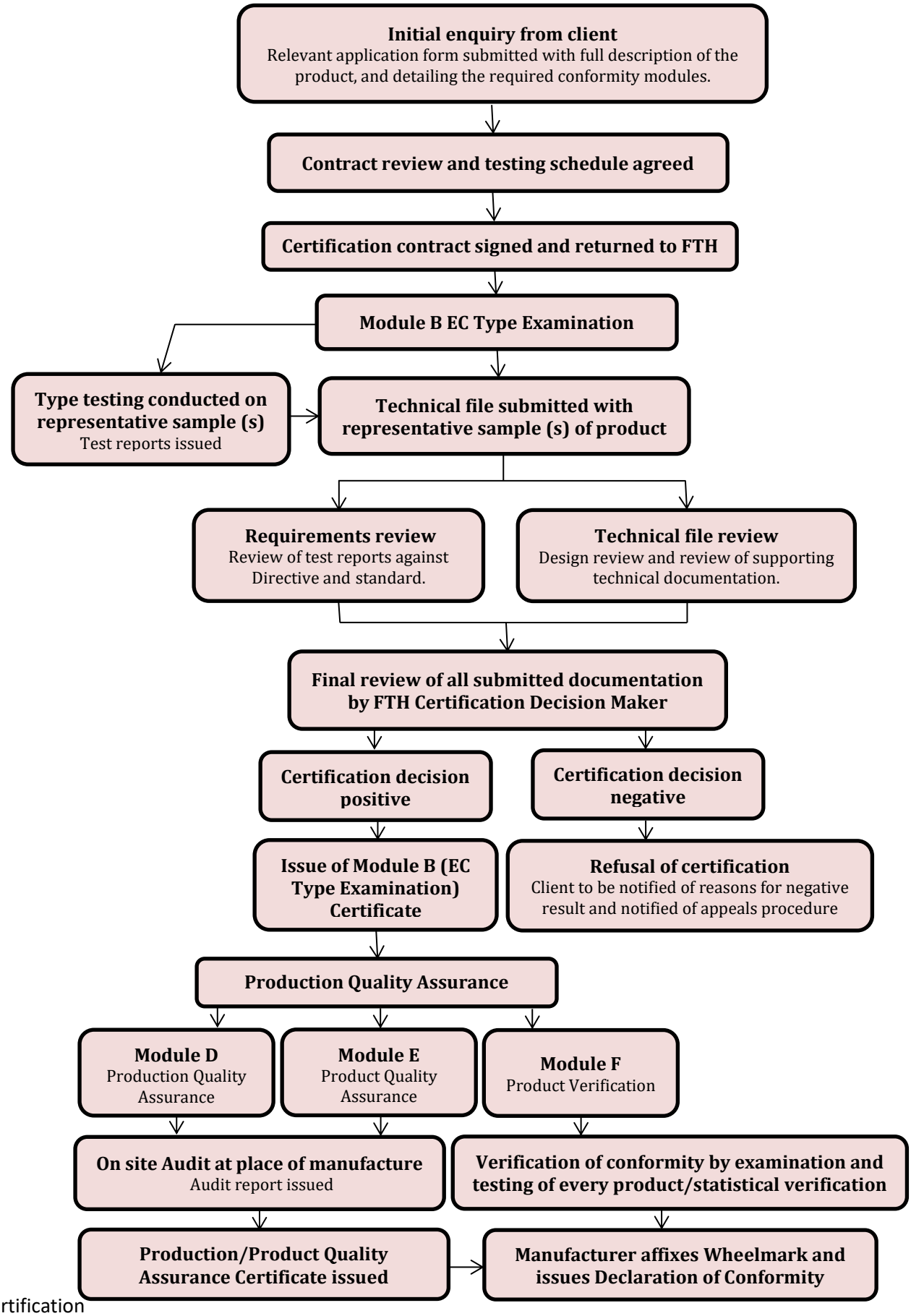
- Product sample inspection and type testing in accordance with the relevant standards listed in the current Implementing Regulation (as applicable);
- Review of a technical file and supporting documentation; and
- Assessing a quality control system for production conformity modules.

Routes to Conformity with the MED

For the scope of marine equipment that FNB cover (lifejackets, immersion suits, TPA'S and lifebuoys) a Module B (EC-Type Examination) certificate is necessary for conformity. Before being placed on the market, the marine equipment must also conform to one of the other production modules:

- Module D (Production Quality Assurance); or
- Module E (Product Quality Assurance); or
- Module F (Product Verification).

Fleetwood Notified Body MED Certification Process



Product Conformity with the MED: Module B

EC type-examination is the part of a conformity assessment procedure in which a NB examines the technical design of marine equipment and verifies and attests that the technical design of the marine equipment meets the relevant requirements of the MED. This involves the following procedures by the Notified Body:

(a) **Examination of a specimen, representative of the production envisaged:** The NB shall verify that the product has been produced in accordance with the manufacturer's technical file and will include the necessary type testing to establish conformity of the model with the relevant standards or, where no such standards are available, the relevant technical specifications.

(b) **Examination of the manufacturer's technical documentation**: The NB shall examine the technical documentation to assess the conformity of the marine equipment with the applicable requirements of the relevant standards or, where no such standards are available, the relevant technical specifications, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and shall cover, as far as relevant for the assessment, the design, manufacture and operation of the marine equipment.

When all requirements are fulfilled FNB will issue an EC Type Examination (Module B) certificate for the product(s).

Quality Assurance Modules: Module D, E or F

The aim of the quality assurance modules is to ensure that the product(s) can be consistently produced in accordance with the type-approval certificate(s).

For Module D and E conformity assessment this is done via an initial review and then by periodical (at least annual) surveillance visits at the locations of manufacture. Module F is applicable to manufacturers whose production is mainly in smaller batches or lots of the same or differing item designations.

Module D – Production Quality Assurance

The audit under Module D shall include a minimum inspection of the following areas:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; and
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

Module E - Product Quality Assurance

The audit under Module E shall include a minimum inspection of the following areas:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the examinations and tests that will be carried out after manufacture;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- the means of monitoring the effective operation of the quality system.

Module F - Product Verification

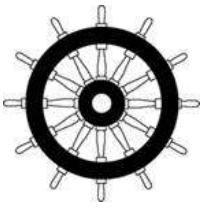
For an audit under Module F the Notified Body carries out the appropriate examinations and tests in order to check that the product complies with the relevant requirements either by examination and testing of every product, or by examination and testing of products on a statistical basis.

EU declaration of conformity for Marine Equipment

This is the process whereby the manufacturer draws up an EU declaration of conformity in accordance with Article 16 and affix the wheel mark in accordance with Articles 9 and 10 of Directive 2014/90/EU, and, under the responsibility of the approving Notified Body for the product / production conformity modules, the NB identification number to each individual product that is in conformity with the approved type described in the EC type-examination certificate and that satisfies the applicable requirements of the standards or technical specifications used as part of the type examination.

This must be kept by the manufacturer for at least 10 years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned.

The Wheelmark



Products certified under the Marine Equipment Directive carry the “wheel mark” as the mark of conformity.

Rules and conditions for affixing the wheel mark:

1. The wheel mark shall be affixed visibly, legibly and indelibly to the product or to its data plate and, where relevant, embedded in its software. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents.

2. The wheel mark shall be affixed at the end of the production phase.

3. The wheel mark shall be followed by the identification number of the notified body, where that body is involved in the production control phase, and by the year in which the mark is affixed.

4. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.

Certificates

When all conformity assessment requirements are fulfilled for the relevant Directive/Regulation, FNB will issue a Type Examination certificate for the product(s). This will remain valid for the life of the certificate (limited to a maximum of five years). After that period, the certificate shall automatically become invalid. The certificate may be renewed, if necessary following retesting/reassessment (see Certificate renewals).

FNB reserve the right to withdraw, restrict or suspend a certificate if:

a) If FNB establishes that a product becomes non-compliant to the applicable requirements set out in the applicable Directive/Standards, it can suspend the certificate or place restrictions on it until such time that the customer guarantees compliance with the requirements again by taking suitable measures;
b) It becomes clear that the holder of the certificate or its representative deceived or attempted to deceive FNB;
c) Misleading or other inadmissible advertising of the certificate is conducted, or the certificate is used improperly or if legal provisions are not complied with when marketing a product;
d) The Directive/Standard requirements are modified rendering the original product tested non-compliant;
(e) The certificate is used for products which do not correspond to the tested type unless otherwise decided by FNB the products are subsequently found to have defects that were not recognised at the time of testing and which, despite a written request by FNB, are not remedied within the stipulated period, or if any other facts become known which would have prevented the issuing of a certificate.

FNB shall have the right to publish the fact that the validity of the certificate has been suspended, restricted or withdrawn.

Use of Fleetwood Notified Body Name and Number

FNB must authorise the use of the Fleetwood Notified Body name and NB identification number and must be used in accordance with the relevant requirements of the applicable Directive/Regulation.

Amendments to Existing Approved Products

Where a client wishes to make an amendment to a product /production process / technical documentation which has previously been certificated by FNB the client must submit an Application for Amendment Form which must include the following information (as relevant):

- Name of manufacturer;
- Name and model of existing product;
- The original FTL reference number/FNB certificate number;
- A detailed description of the changes to the existing product; and
- The reason for amendment.

FNB will review the changes and will determine if any additional type testing is required to ensure continued conformity of the product with the Directive/Regulation, relevant standard or technical specification as applicable.

The technical file documentation must be updated to reflect the changes to the original product and this will be reviewed and approved by FNB.

Once the sufficient documentation is received and correct, FNB will issue a new Type Examination Certificate (if required), and/or a letter of conformity stating that the changes have been accepted and are valid under the original certificate number.

Certificate Renewals

Where a client wishes to renew a type examination certificate the client must submit an Application for Certificate Renewal Form to FNB at least six months prior to the expiry date of the certificate. In addition the following information will be required:

I) Confirmation that the existing technical file may be used in support of the renewal (alternatively a new technical file may be submitted).
II) Supporting documentation to confirm the following:
- Confirmation of the current company name and address;
- Confirmation of current production address(es);
- Confirmation that there have been no changes to the product, including sub-components /sub-assemblies;
- Copies of current product drawings and photographs, product marking and information supplied by the customer;
- The data resulting from the control and test facilities that have been used to check compliance of the PPE with the harmonised standards and / or other technical specifications;
- For category III products information on Module C2/Module D status;
- In addition to the above at least one piece of the product described in the certificate which represents current production shall be submitted.
- The customer is free to submit any additional documents to support the application for renewal, e.g. independent product certifications, independent quality system certifications, etc.

FNB will review any changes and will determine if any additional type testing or additional documentation is required to ensure continued conformity of the product with the Directive/Regulation, relevant standard or technical specification as applicable.

The technical file documentation must be updated to reflect any changes to the original product and this will be reviewed and approved by FNB.

Once the sufficient documentation is received and correct, FNB will issue a new Type Examination Certificate.

Please contact us if you have any additional questions regarding our certification schemes.