FLEETWOOD TEST HOUSE

FLEETWOOD NOTIFIED BODY

Certification Schemes

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FLEETWOOD TEST HOUSE

Section 1: 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.

In January 2020 the UK left the European Union and December 31st 2020 saw the end of the withdrawal agreement transition period. From 1st January 2021 a new UK product conformity assessment scheme came into force for PPE and Marine Equipment. Existing UK Notified Bodies (including FNB) were no longer recognised as EU Notified Bodies and became UK Approved Bodies. This marked a significant change to the certification schemes offered by FNB and we now offer conformity assessment for the UKCA product approvals for PPE, and UK Red Ensign approvals for Marine Equipment.

Section 2: Fleetwood Test House – Certification Schemes

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

- Personal Protective Equipment Regulations (Regulation 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018.
- The Merchant Shipping (Marine Equipment) Regulations 2016 as amended.

Scope of Products:

FTH offers testing* and certification for the following PPE products:

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

We also offer testing* and certification for the following Marine Equipment/Life Saving Appliances (LSA):

- Lifejackets
- Immersion Suits
- Thermal Protective Aids
- Lifebuoys

Our notification as a UK Approved Body can be found on the UK list of Conformity assessment bodies at the following link: https://www.gov.uk/uk-market-conformity-assessment-bodies.

***Testing is performed by Fleetwood Testing Laboratory which is an ISO 17025:2017 accredited testing laboratory, accredited by the United Kingdom Accreditation Service (UKAS). UKAS testing laboratory number 1559.**

Section 3: Personal Protective Equipment Regulations (Regulation 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018

The Personal Protective Equipment Regulations (Regulation 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 is the new UK legislative framework that came into force on the 1st January 2021 and it covers the manufacture and marketing of personal protective equipment placed on the market in Great Britain (England, Wales and Scotland). It defines legal obligations to ensure that PPE provides the highest level of protection against hazards.

Please note that there is a separate procedure for placing product on the Northern Ireland market, please refer to the Northern Ireland Protocol and UKNI marking in Section 9.

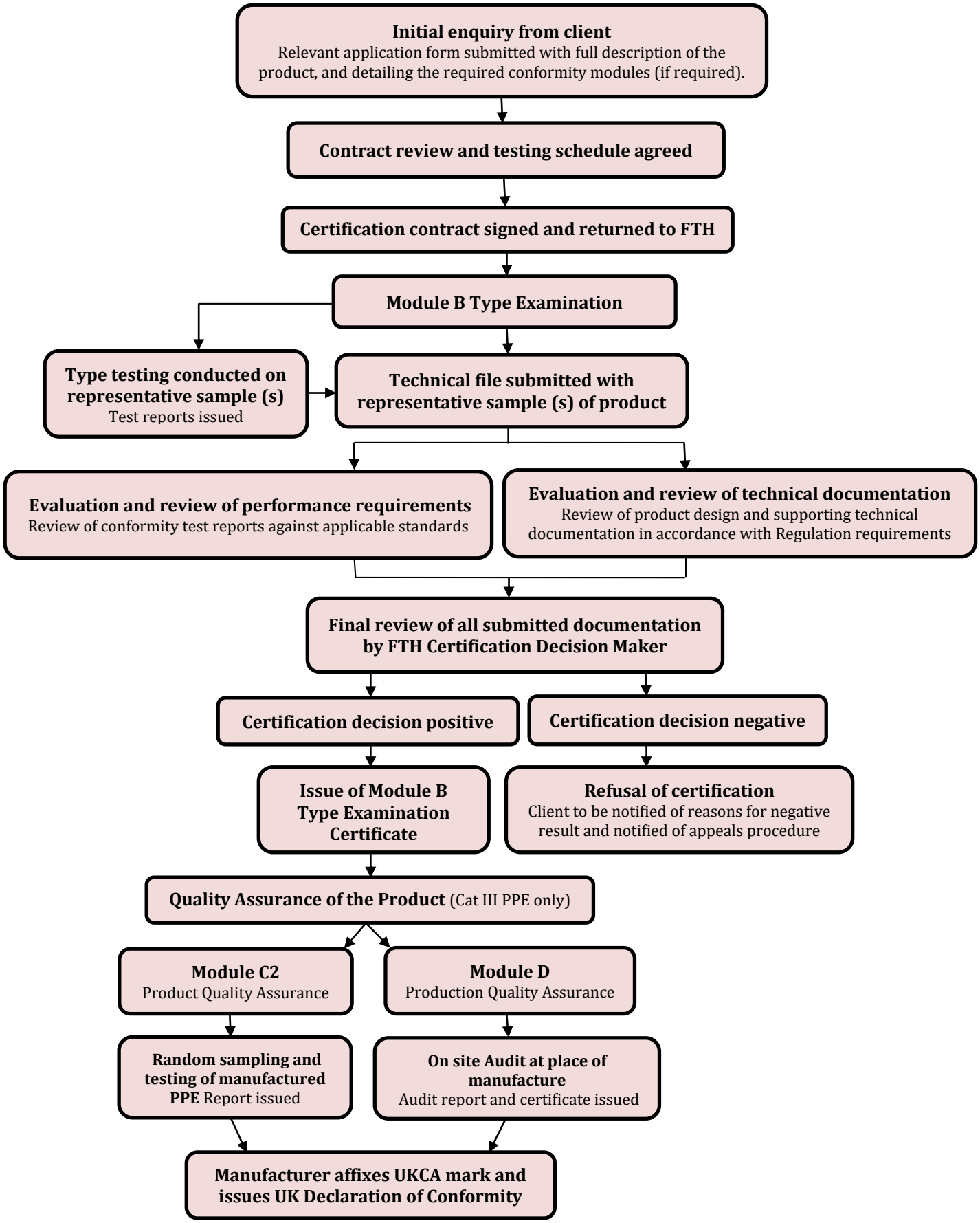
The essential requirements you must meet, and the conformity assessment processes and standards that can be used to demonstrate conformity under the UKCA scheme are largely the same as they were for the CE marking under the PPE Regulation 2016/425 except, the CE marking has been replaced by the UKCA (UK Conformity Assessment) mark to provide evidence of this protection*.

FNB's new appointment as a UK approved body means that we can offer product conformity assessment of risk category II and III PPE to the new UKCA scheme, including the following:

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

*There is an interim period between the 1st January 2021 and the 31st December 2022 where the UK will accept CE marking for placing PPE on the market in Great Britain.

Section 4: Fleetwood Notified Body PPE Certification Process



Section 5: PPE Product Conformity: Module B Type-Examination

Module B Type-examination is the procedure whereby the approved body establishes and certifies that the PPE model in question satisfies the relevant provisions of the PPE Regulation. This involves the following procedures:

(a) **Examination of the manufacturer's technical documentation**: The approved body shall examine the manufacturer's technical file to establish its suitability with respect to the relevant designated 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 approved body 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 designated standards or, where no such standards are available, the relevant technical specifications covering the EHSR of the PPE Regulation.

Section 6: PPE Product Conformity: 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 type-approval certificate and with the EHSR requirements of the PPE Regulation. This involves checking of the PPE by the approved body by:

- **Module C2. 'Conformity to type based on internal production control plus supervised product checks at random intervals:** The approved body 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;
- **Module D. 'Conformity to type based on quality assurance of the production process:** The approved 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 normally carried out at intervals of at least once per year and an approved body will issue a report to show the conclusions of the inspection and, if required, a production quality assurance certificate.

Section 7: UK Declaration of Conformity for PPE

The UK declaration of conformity is the procedure whereby the manufacturer or his authorized representative draws up a declaration certifying that the PPE placed on the market are in conformity with the provisions of the Regulation and affixes the UKCA mark to each PPE.

Section 8: UKCA Marking

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

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

- UKCA markings must only be placed on a product by the manufacturer or authorised representative (where allowed for in the relevant legislation).
- when attaching the UKCA marking, the manufacturer takes full responsibility for the product's conformity with the requirements of the relevant legislation.
- the UKCA marking must only be used to show product conformity with the relevant UK legislation.
- the manufacturer must not place any marking or sign that may misconstrue the meaning or form of the UKCA marking to third parties.
- the manufacturer must not attach other markings on the product which affect the visibility, legibility or meaning of the UKCA marking.
- the UKCA marking cannot be placed on products unless there is a specific requirement to do so in the legislation.

<u>Rules for using the UKCA image</u>

- If the mark is reduced or enlarged, the letters forming the UKCA marking must be in proportion to the version set out above.
- The UKCA marking is at least 5mm in height.
- The UKCA marking is easily visible and legible.

Section 9: Northern Ireland Protocol and UKNI Marking

The Northern Ireland Protocol came into force on 1 January 2021. For as long as it is in force, Northern Ireland will align with relevant EU rules relating to the placing on the market of manufactured goods, which means in Northern Ireland, EU conformity markings (the CE mark) continues to be used to show that goods meet EU rules. Therefore, if you have a CE approval issued by an EU Notified Body, you do not need a separate UKNI mark.

If you require mandatory third-party conformity assessment from a UK conformity assessment body, and you do not already have CE approval with an EU Notified Body, then you also need to apply a UKNI marking. You never apply the UKNI marking on its own, it always accompanies an EU conformity CE marking. Please note that goods approved by a UK conformity assessment body with both the CE and UKNI marking cannot be placed on the market in the EU. For more information please see https://www.gov.uk/guidance/using-the-ukni-marking.
FNB can offer certification for the UKNI/CE marking for the Northern Ireland market.

UK
NI

The following general rules apply:

- The UKNI marking must only be placed on a product by the manufacturer or the authorised representative (where allowed for in the relevant legislation).
- When attaching the UKNI marking to accompany another conformity marking, the manufacturer takes full responsibility for the product's conformity with the requirements of the relevant legislation.
- The manufacturer must not place any marking or sign that may misconstrue the meaning or form of the UKNI marking to third parties.
- The manufacturer must not attach other markings on the product which affect the visibility, legibility or meaning of the UKNI marking.
- The UKNI marking cannot be placed on products unless there is a specific requirement to do so in the legislation.
- The UKNI marking must accompany another conformity marking; it never appears on a product alone.

Rules for using the UKNI image

- If the mark is reduced or enlarged, the size of the marking letters forming the UKNI marking must be in proportion to the version set out below.
- The UKNI marking is at least 5mm in height – unless a different minimum dimension is specified in the relevant legislation
- The UKNI marking is easily visible, legible, and permanently attached if the mark is reduced or enlarged, the letters forming the UKCA marking must be in proportion to the version set out above.

Declaration of Conformity

The manufacturer must supply an EU Declaration of Conformity for PPE lawfully bearing a UKNI and CE.

Section 10: The Merchant Shipping (Marine Equipment) Regulations 2016

From the 1st January 2021, the Merchant Shipping (Marine Equipment) Regulations 2016 as amended came into force along with MSN 1874 (M+F) Amendment 4, which set out performance and testing standards to be met by marine equipment placed or to be placed on board a UK ship in accordance with the UK's conformity assessment procedures.

Please note that there is an interim period until 1 January 2023, where the UK will accept marine equipment holding MED conformity approval granted by one or more EEA Notified Bodies, bearing the MED conformity mark and otherwise compliant with the MED provided MED and UK standards remain equivalent.

FNB is appointed as a UK Approved Body for the purposes of conformity assessment tasks for marine equipment in the UK and we cover conformity assessment of marine equipment under the category of Life Saving Appliances (LSA), specifically lifejackets, immersion suits, TPA'S and lifebuoys, including the following activities:

- Product sample inspection and type testing in accordance with the relevant standards listed in Annex 1 of MSN 1874 (M&F), Amendment 4 (as applicable);
- Review of a technical file and supporting documentation; and
- Assessing a quality control system for production conformity modules.

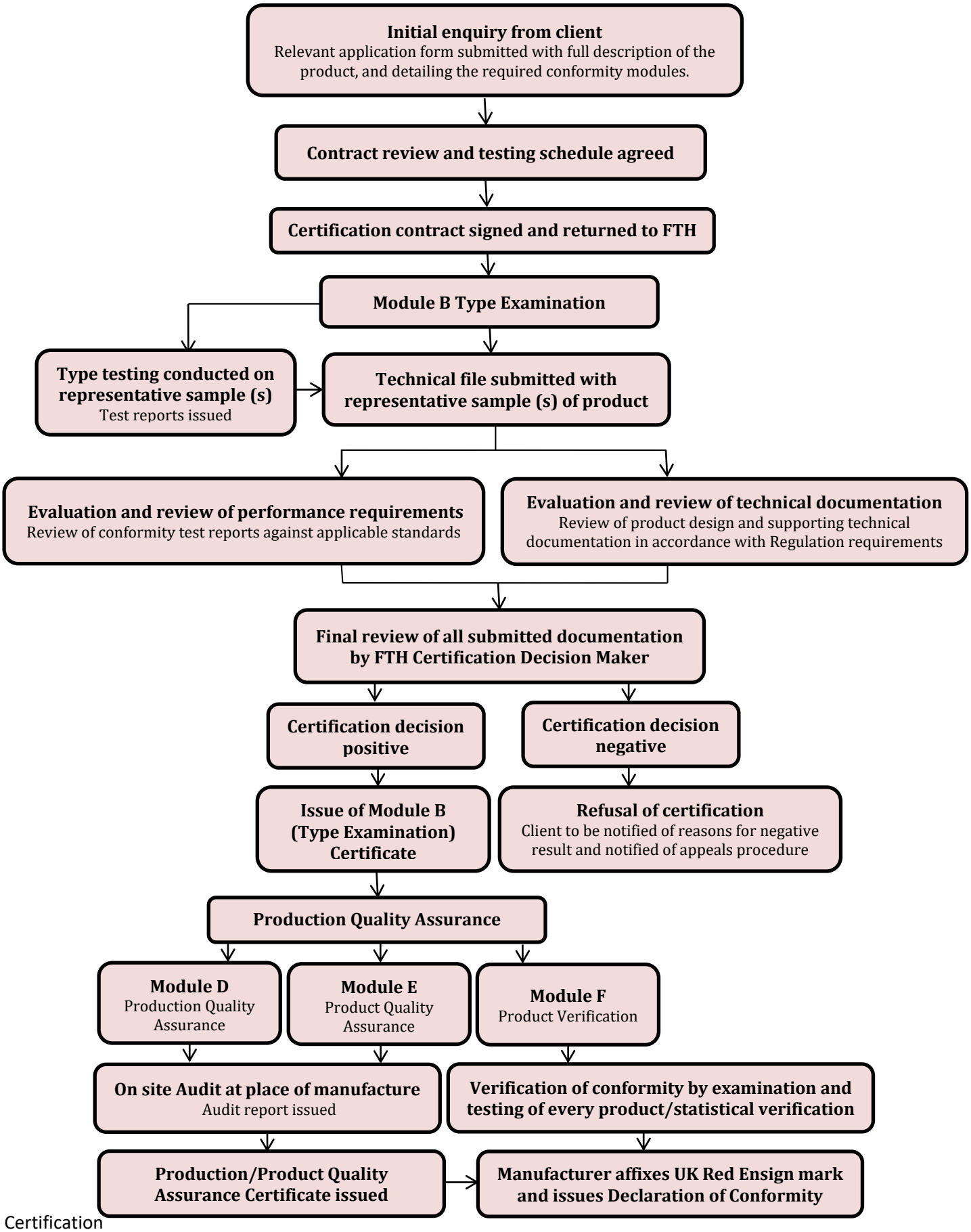
The UK conformity assessment procedures for marine equipment applies for all UK approved equipment manufactured or installed on board UK ships in Northern Ireland, including UK ships with their home port in Northern Ireland.

Section 11: Routes to Conformity for Marine Equipment

For the scope of marine equipment that FNB cover (lifejackets, immersion suits, TPA'S and lifebuoys) a Module B (Type Examination) certificate is necessary for conformity in addition to one of the other production modules:

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

Section 12: FNB Marine Equipment Certification Process Flowchart



Section 13: Marine Equipment Product Conformity: Module B Certification

Module B certification (type-examination) is the part of a conformity assessment procedure in which an approved body examines the technical design of marine equipment and verifies and attests that the technical design of the marine equipment meets the relevant performance requirements. This involves the following procedures:

(a) **Examination of a specimen, representative of the production envisaged:** The approved body 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 approved body 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 a Type Examination (Module B) certificate for the product(s).

Section 14: 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 approved 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.

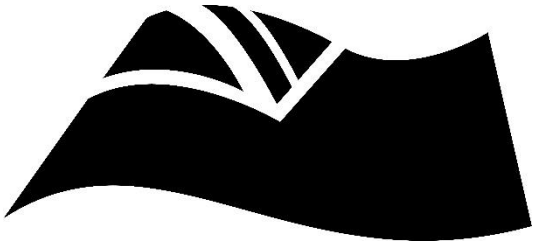
Section 15: UK declaration of conformity for Marine Equipment

This is the process whereby the manufacturer draws up a UK declaration of conformity and affixes the UK conformity mark (which is detailed in Annex 5 of MSN 1874 (M+F) Amendment 4) and, under the responsibility of the approving body for the product / production conformity modules D, E or F, applies the approved body identification number to each individual product that is in conformity with the approved type described in the Module B Type-examination certificate.

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

Section 16: The UK conformity mark (Red Ensign)

Products certified under the Merchant Shipping (Marine Equipment) Regulations 2016 carry the "Red Ensign" as the mark of conformity. This can be used in the following forms:



Rules and conditions for affixing the UK conformity mark:

The UK conformity mark must be affixed in the same way as the wheel mark on MED approved products including but not limited to:

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

3. The 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.

Section 17: Certificates

When all conformity assessment requirements are fulfilled for the relevant certification scheme, 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 section 20 Procedure for 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 Legislation/Standard, 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 Legislation/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.

Section 18: 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 Certification Scheme.

Section 19: Application for 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 legislation, 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.

Section 20: Procedure for Certificate Renewal

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 legislation, 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.