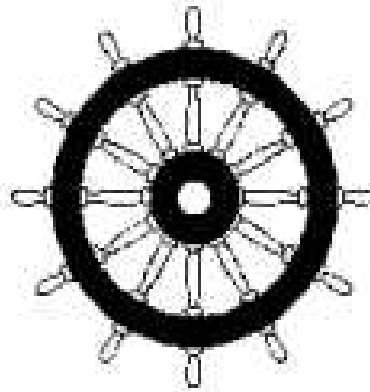


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 **BABT 741**

**A Guide to the BABT Implementation of  
the Marine Equipment Directive  
(96/98/EC) Module F (Product  
Verification)**

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BABT is the telecommunications  
certification body of



## **Foreword**

This guide describes the BABT Implementation of Module F ( Product Verification) of the Marine Equipment Directive (MED), 96/98/EC.

This guide should be read in conjunction with BABT 740 which overviews the BABT Implementation of Modules B, D, E, F and G of the Marine Equipment Directive (MED) [96/98/EC].

The implementations of Module D and E are explained in more detail in BABT AP008

This guide is designed so that the essential information can be read quickly by reading the main text only. Where you require more information, refer to the shaded sections.

The scheme enables a manufacturer of product within the scope of the MED to affix a Wheel mark including the BABT Notified Body number after satisfying the appropriate module(s) of the MED.

The formal requirements of the scheme are set out in this guide and in the Certification Regulations.

All BABT publications are available from:

**<http://www.babt.com>**

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The BAPT Implementation of the MED including Modules B, D, E, F, and G are detailed in BAPT 740 which should be reviewed before reading this document

## 1. Introduction

### 1.1 Scope

This guide overviews the BAPT Implementation of Module F (Product Verification) of the Marine Equipment Directive (MED) [Refer to Directives 96/98/EC; and the current effective amendment.

### 1.2 Overview

The MED provides for a number of alternative routes to meet the requirements of the directive.

The routes available for particular equipment are dependant upon the standards invoked by the category and nature of the equipment. Refer to MSN 1734 for full details.

Module F is intended to interwork with Module B (Type Examination) of the directive. A certificate to Module B is a requirement for a Module F certificate to be generated.

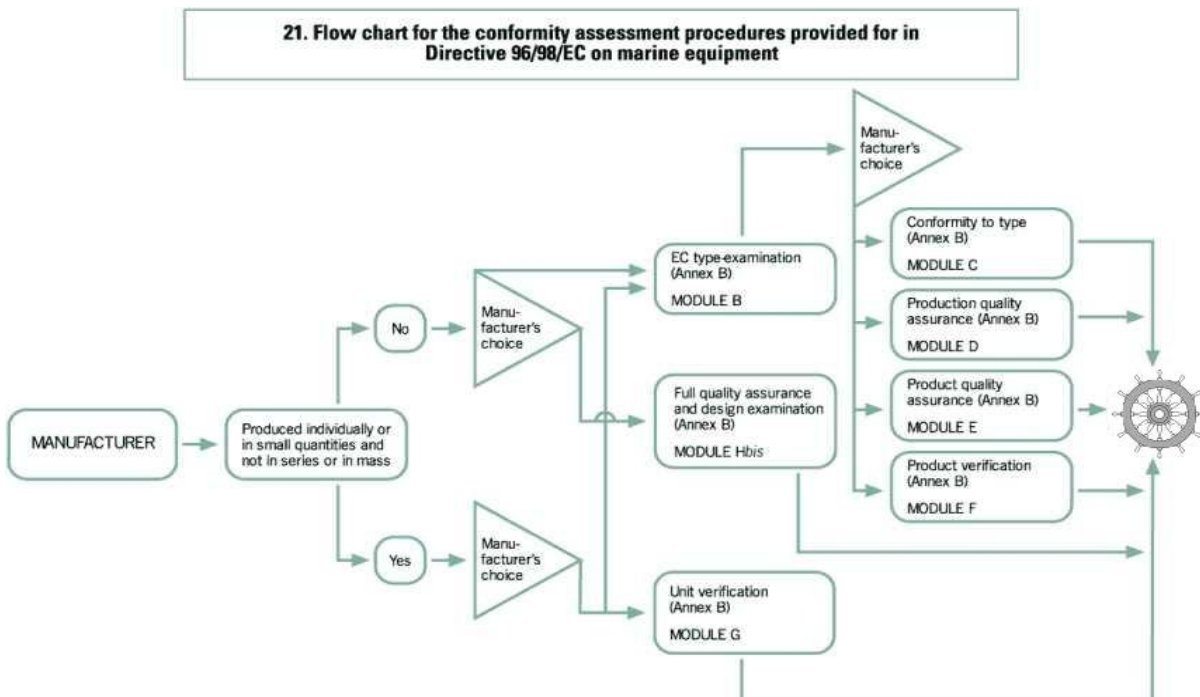
Under Module F you identify the number of product items you intend to manufacture within a specified time (e.g. a lot or batch size). A product sampling plan and test/inspection plan is then agreed with the notified body. Obligations remain upon the manufacturer with respect to individual unit inspection and test product marking, and record retention. The formal requirements for the scheme are listed in MSN 1734 (Annex B). Where a sample shows compliance you may request a Module F certificate for that lot from the responsible notified body.

The BAPT implementation of this Module is split into 2 parts:

1. An Application for a Product Verification agreement which permits production
2. Applications for Individual Module F Product Verification Certificates covering a defined number of items of a product.

The purpose of the agreement is to establish the testing strategy, and overall product aspects. General BAPT monitoring occurs under this agreement.

Requests for individual Product Verification Certificates may then be made with data which relates to that particular batch of items, under the general agreement.



## 1.3 Definitions and Terms

### Manufacturer

A manufacturer is the person who is responsible for designing and manufacturing a product with a view to placing it on the Community Market on his own behalf.

The Manufacturer has an obligation to ensure that a product intended to be placed on the community market is designed and manufactured, and its conformity assessed to the essential requirements.

The Manufacturer must always retain the overall control and have the necessary competence to take responsibility for the product.

### Authorised Representative

The Manufacturer may appoint any natural or legal person to act on his behalf as an Authorised Representative. The Authorised Representative must be established inside the community. An Authorised Representative may be addressed by the authorities of the Member states instead of the manufacturer with regard to the latter's obligations under this directive.

The Manufacturer remains generally responsible for actions carried out by an Authorised Representative on his behalf

### Importer

An importer (a person responsible for placing the product on the market) is any natural or legal person established in the community who places a product from a third country on the community market. The importer must ensure that he is able to provide the market surveillance authorities with the necessary information regarding the product where the manufacturer is not established in the community and has no Authorised Representative in the community.

### Agent

An Agent is a natural or legal person, established either within the community or elsewhere in the world, appointed by the manufacturer to act on his behalf with respect to the application. Where the Agent is not the nominated Authorised Representative the application must include a letter from either the Manufacturer or the Authorised Representative authorising BAPT to communicate with the Agent for matters related to the application

### Applicant

The applicant must be either the Manufacturer or the Authorised representative. An Application may not be made by an Agent who is not also the Authorised Representative.

## 2. MED Module F (Product Verification) Requirements

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### 2.1 Introduction

The following requirements are derived from the requirements for MED Module F. They have been presented in sections as follows:

- Requirements for application to BAPT for a Product Verification agreement
- Requirements for a Module F Product Verification Certificate of Conformity from BAPT
- Requirements after issue of a Module F certificate
- Monitoring by BAPT

### 2.2 Extract of Module F

The following extract from the MED details the formal requirements of the MED Module F.

#### PRODUCT VERIFICATION (MODULE F)

1. A manufacturer or his authorized representative established within the Community must check and attest that the products subject to point 3 conform to the type as described in the EC type-examination certificate.
2. The manufacturer must take all measures necessary to ensure that the manufacturing process ensures that the products conform to type as described in the EC type examination certificate. He must affix the mark to each product and must draw up a declaration of conformity.
3. The notified body must carry out the appropriate examinations and tests in order to check that the product complies with the requirements of the international instruments either by examination and testing of every product as specified in point 4 or by examination and testing of products on a statistical basis, as specified in point 5, at the choice of the manufacturer.
- 3a. The manufacturer or his authorized representative established within the Community must keep a copy of the declaration of conformity for at least 10 years after the last product has been manufactured.
4. Verification by

examination and testing of every product

4.1 All products must be individually examined and appropriate tests must be carried out in order to verify their conformity to type as described in the EC type-examination certificate.

4.2 The notified body must affix its identification symbol or cause it to be affixed to each approved product and draw up a written certificate of conformity relating to the tests carried out.

4.3 The manufacturer or his authorized representative established within the Community must ensure that he is able to supply the notified body's certificate of conformity on request to the flag Member State administration.

#### 5. Statistical verification

5.1 The manufacturer must present his products in the form of homogeneous lots and must take all measures necessary to ensure that the manufacturing process ensures the homogeneity of each lot produced.

5.2 All products must be available for verification in the form of homogeneous lots. A random sample must be drawn from each lot.

Products in a sample must be individually examined and appropriate tests must be carried out to ensure that they comply with the requirements of the international instruments which apply to them and to determine whether the lot is to be accepted or rejected.

5.3 In the case of accepted lots, the notified body must affix its identification symbol or cause it to be affixed to each product and must draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which are found not to comply.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent that lot's being put on the market. In the event of frequent rejection of lots the notified body may suspend statistical verification. The manufacturer may, under the responsibility of the notified body, affix the latter's identification symbol during the manufacturing process.

5.4 The manufacturer or his authorized representative established within the Community must ensure that he is able to supply the notified body's certificates of conformity on request to the flag Member State administration.

### 3. Making and progressing an application to for a Product Verification agreement.

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#### 3.1 General

##### 3.1.1 Purpose

The purpose of the agreement is to establish the testing strategy, and overall product aspects. General BABT monitoring may also occur under this agreement.

A valid Product Verification agreement must be in place prior to any production of any equipment to be certified by BABT using this module.

##### 3.2 How to apply

The application is an order for BABT's certification services and should be made by e-mail or on a CD to BABT Customer Service. (Refer to the forward for details) direct to BABT in Octagon House.

Applications will be accepted by post, or email, to [customer.services@babt.com](mailto:customer.services@babt.com).

The application must be made using form BABT 776 and must be accompanied by the required information to support the assessment.

On receipt of your application, BABT will generate and send you a confirmation of the application.

Where TUV Product Service Ltd have taken the order for testing and certification you should discuss with your

contact the best way to deliver the application to BABT.  
Regular Customers of BABT may request an FTP upload address as an alternative to e-mail or post but must advise BABT Customer service when an application is fully uploaded.

### 3.3 Who can apply

An Application for an agreement must be made by or on behalf of the holder of at least one of the Module B TECs which are to be included in the agreement.

### 3.4 Information required on and with the application form

#### 3.4.1 Applicant Contact Details

You must provide the following details of the applicant

- The full company name
- The address of the Main Contact
- Their telephone, fax and e-mail details.
- An indication whether they are the manufacturer or an Authorised Representative
- Name of a contact within the applicant company with any title (e.g. Mr.)
- Job title (or role within the organisation)

Note: The agreement is issued to the Company name and address detailed as the applicant. If any variation is required ( e.g. Different building address) please contact BABT with a justification for variation.

#### 3.4.2 Other Contact Information

Where an application is made on behalf of the manufacturer (e.g. in their company name) by an Authorised representative you must provide contact details of the Authorised Representative .

If you wish to identify a consultant to be involved with your application please indicate this on the application form and provide, on company headed paper signed by the main contact, details of the consultant and his role.

#### 3.4.3 Type of Agreement

Please indicate whether you intend testing every item or whether you intend employing a sampling plan.

Also please identify whether this is a new agreement or a modification to an existing one.

#### Modifications

An agreement will require modification if the company name or address changes; if the product name changes, or the test plan or sampling plan changes. BABT also require advice if a TEC from another Notified Body has been varied (BABT will review the change and will advise you whether the Agreement must be modified).

#### 3.4.4 Product Details

Please list the names of the products to be covered by this agreement.

You must include the Module B TEC number for every product to be included in the agreement.

Where you list a Module B TEC which was issued by another Notified Body tyou must include a copy of that TEC and any Annex with the application.

#### Listing Products with Different Module B TEC Holders or Manufacturers in a single agreement

It is understood that Brandname products may be electrically and functionally identical to the original product. Such products may be included in your application for an agreement by the Applicant provided you can justify their inclusion. Note however only the Agreement Holder can request modifications to the agreement. Note: Separate applications for the Module F Certificates will be necessary as they are linked to specific Module B TECS.

#### Note:

Where either the test plan or sampling plan differs between models a separate Agreement is required

Please provide details of the type of product which most closely matches your product.

#### 3.4.5 Number of Production items

Please provide an estimate of the number of items you expect to produce in a year and an estimate of the Lot/Batch sizes you expect using for the Certificate of Conformity.

**Lot/Batch size** may vary in actual production. The predicted size is to confirm the sample plan is appropriate.

**Sample Size:** For small batch sizes, or where a single failure results in a whole batch being 100% tested BAPT will normally accept a single item to be tested per batch.

**Brand named Products:** Where you have included brand named products in the Agreement please identify whether the numbers provided cover the whole production, or the production for a given Brandname.

### 3.4.6 Test Plan

You must include your test plan for the production items.

This should include

- Details of the testing to be performed and include:
  - List of all relevant tests to be performed with the pass/fail criteria and a reference to the relevant requirement from the type testing; and
  - List of which tests are to be performed on every production item
  - List of which tests are to be performed on the selected sample (where relevant).
- Details of your proposed location for the tests with any required criteria (e.g. Accredited Lab for the Sample testing, Production facility for the tests on all items);
- List of any special test equipment to be used and the controls in its use (e.g. Automatic Test Machine(ATM) owned/controlled by the Holder, with its calibration method/schedule)

This document must be issue controlled and under the release control of the holder.

#### Unaccredited Testing

Unaccredited Testing includes testing in Accredited test laboratories testing outside their accredited scope,, testing at your own design or testing facilities( except where they are separately accredited) , and testing performed at the location of the final assembly of the product

Where you propose testing the product at an unaccredited location the following additional requirements will apply.

- The results must be reported in a summary test report following the requirements of ISO/IED 17025 Clause 5.10
- Where you have used any test method not specified in a standard you must provide details of the test method followed (either directly in the test plan or referenced to a separately included document )
- You must provide details of the competence criteria for the personnel who will be performing the test ( e.g. experience/training/qualification); with a statement of their competence in any test report
- You must provide details of test equipment intended to be used; the test report must detail such equipment with their calibration status at the time of test;
- You must specify in the plan how you will ensure the accuracy of the test set-up throughout the testing ( e.g. ATM Self testing, testing “Golden samples”, Just Fail tests etc) ; brief details of the results of these tests must be included in the test report

### 3.4.7 Sampling Procedure

This is only required where you opt to perform sampling rather than 100% testing of the batch.

As a minimum this procedure shall cover

- the method for the selection of the sample;
- the proposed lot/ batch size
- the process to obtain the results; and
- the process to be followed if any of the sample fail to meet the requirements.

This document must be issue controlled and under the release control of the holder.

#### Extract from NB-MarED recommendation

**For information -**

Extract from ISO 2859-1 (BS 6001 Pt 1) Sampling procedure for inspection by attributes.  
Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

**Definition**

**Lot:** A collection of units of product from which a sample shall be drawn and inspected to determine conformance with the acceptability criteria and which may differ from a collection of units designated as a lot for other purposes (for example, production, shipment, etc.)

**Sample:** A sample consists of one or more units of product drawn from a lot, the units of the sample

being selected at random without regard to their quality, The number of units of product in the sample is the sample size.

**Submission of product for sampling**

**Formation of Lots:** The product shall be assembled into identifiable lots, sub-lots, or in such other manner as may be laid down (see below). Each lot shall, as far as is practicable, consist of units of product of a single type, grade, class, size and composition, manufactured under essentially the same conditions and at essentially the same time.

**Presentation of lots:** The formation of the lots, the lot size and the manner in which each lot shall be presented and identified by the supplier shall be designated or approved by, or according to, the responsible authority,. As necessary, the supplier shall provide adequate and suitable storage space for each lot, equipment needed for proper identification and presentation, and personnel for all handling of product required for drawing of samples.

**Drawing of samples**

Representative sampling: When appropriate, the number of units in the sample shall be selected in proportion to the size of sub-lots of the lot, identified by some rational criterion.

**Inspection level**

The inspection level required for any particular application shall be prescribed by the responsible authority.

**3.4.8 Sampling Plan**

Where the sampling option is selected the sampling process should be based upon industry recognised sampling plans.

The following are examples of a sampling procedures:

- BS6001-0 ( ISO 2859-0)
- BS6001-1 (ISO 2859-1)
- IEC 410
- ANSI/ASQ Z1.4

BABT will review the plan but may need details of the industry standard/practice from which they are derived.

Note: Options within a standard which permit an automatic pass with any failure rate are not acceptable.

**3.4.9 Payment Details**

Please complete this information as appropriate to your option

Note: Where you have accepted a quotation from a TUV Sud office which includes this BABT Certification application you do not have to complete this section

**3.4.10 Agreement**

This agreement forms the contract between the BABT Certification body and you. It will normally be signed by the main contact. Where another person (e.g. A Senior Manager) within the company signs, brief details of their role related to the application should be provided with the application.

Where the manufacturer is the holder an Authorised Representative may also sign on their behalf provided the representative is either named in the Module B TEC certificate or this application includes a letter from the holder identifying them as the Authorised representative.

**3.5 Progressing the Product Verification agreement**

**3.5.1 Initial receipt**

When BABT has received your application we will:

- evaluate the initial information
- send you a confirmation of your order detailing our understanding of your application
- ask you to pay an application fee
- inform you of the BABT reference number assigned to your application. This number should be quoted in all further correspondence.

### **3.5.2 Assessment of Documentation**

BABT will review the Test plan and the sampling process/procedure against the relevant TEC(s).

Should the allocated BABT engineer require further information or clarification this will be addressed to the identified contact person.

When the BABT Engineer is satisfied the requirements are met a Product Verification agreement will be issued for that Product. This agreement will entitle the applicant to apply Module F Product Verification Certificates for that product under that agreement.

The Production Verification agreement is valid for 5 years and is not subject to any annual fee. However modifications to the agreement will be charged for appropriate to the work involved.

## **4. Making and progressing an Application for a MED Module F Product Verification Certificate of Conformity**

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### **4.1 General**

Applications for a MED Module F Product Verification Certificate of Conformity shall be made with data which relates to that particular batch of items, under a Product Verification agreement.

These requirements have to be met at the time of application to BABT for a Module F Product Verification Certificate.

Normally this request will relate to a given lot.

A request for a certification of more than one lot may be made provided the accompanying information relates to each specific lot.

#### **4.1.1 Application**

You should apply for a Product Verification Certificate of Conformity using form BABT 781 accompanied by the required information.

The Application should be made by e-mail or on a CD to BABT Customer Service. (Refer to the forward for details).

The Application shall normally be made by or on behalf of either the company named in the Product Verification Agreement, or by one of the Holders of a TEC listed in the agreement

Application may also be made by or on behalf of a holder of a Module B TEC for a product which is a brand name of one of the products listed in the agreement.

#### **4.1.2 Who can apply**

An Application for an Module F Certificate of Conformity must be made by or on behalf of the holder of the related Module B TEC referenced in the application.

## **4.2 Information required on and with the application form**

### **4.2.1 Applicant Contact Details**

You must provide the following details of the applicant

- The full company name
- The address of the Main Contact
- Their telephone, fax and e-mail details.
- An indication whether they are the manufacturer or an Authorised Representative
- Name of a contact within the applicant company with any title (e.g. Mr.)
- Job title (or role within the organisation)

Note: The agreement is issued to the Company name and address detailed as the applicant. If any variation is required ( e.g. Different building address) please contact BABT with a justification for variation.

### **4.2.2 Other Contact Information**

Where an application is made on behalf of the manufacturer (e.g. in their company name) by an Authorised representative you must provide contact details of the Authorised Representative .

If you wish to identify a consultant to be involved with your application please indicate this on the application form and provide, on company headed paper signed by the main contact, details of the consultant and his role.

#### **4.2.3 Module B TEC, Agreement References and request for a US Coast Guard number**

Please indicate the Module B TEC number of the product to be certified. Where this has been issued by another Notified Body please indicate their number as “(xxxx)” [ i.e. the TUV Product Service number would be shown as “(1895)” {Note TUV is an NB under the LVD and EMC Directives but not the Marine Equipment Directive }

Please list the BABT Reference of the Product Verification Agreement under which this application is being made. Please include the issue date of the agreement.

Where the product is not listed in the Product Verification Agreement but is a brand name of one that is listed the application must include a brief justification of why the agreement may be applied to the product. (This may be combined in the permission to use the Agreement letter)

Under the EU-USA MRA ( EC decision 2004/425/EC) BABT may allocate US Coast Guard approval numbers for certain Navigation products.

Where applicable please indicate when you wish BABT to allocate a USCG number on the Module F Certificate of Conformity.

#### **4.2.4 Commercial Details**

Please complete this information as appropriate.

Note: Where you have accepted a quotation from a TUV Sud office which includes this BABT Certification application you do not have to complete this section

#### **4.2.5 Product Details**

Please list the names of the products to be covered by this agreement.

You may only identify more than one product name where all names are listed on the Module B Type examination Certificate. You must include the sample selection criteria taking into consideration all required items.

Please list details of the means to identify those products falling within all Lots to be covered by the Product Verification Certificate. This may be a sequential set of serial numbers; serial numbers which include a lot identity; or other means to identify whether a given product is covered by the certificate being applied for.

- Where you have opted to test each item then each Serial number must be listed (or a range listed)
- Where you have opted to test following a sampling plan then you must include details of each lot size.

It is important that the identification information be clearly specified such that it may be correlated to the total number of items. The following examples are provided to assist you.

*	Type of identification:	Serial numbers.	Numbers 1001 -2000	(This covers 1000 items)
*	Type of identification:	Serial Numbers.	Numbers XXL500xxxx	where xxxx = 0000 to 5000 (this specifies 5001 numbers, where the intended lot size may be 5000)
*	Type of identification:	Batch Numbers.	Numbers EU01 to EU10.	(The batch size is required to correlate with the total number of items)
*	Type of identification:	Date Codes:	Dates: May 1999, June 1999.	(Details of how the manufacturing numbers will be controlled should be provided.)

Where there is insufficient space to identify the lots, or you hold the information in a different format please indicate the document identity on the form and provide the relevant document with the application.

#### **4.2.6 Reports of Testing**

Please list the identities of the test reports supporting this application. Refer later for further details related to testing and test reports.

#### **4.2.7 Declaration of Conformity**

Please include a draft Declaration of Conformity for the items/lots to be covered by the Product Verification Certificate.

BABT will check this for consistency with this application but will not necessarily delay issuing a Product Verification Certificate if concerns are raised about the DoC.

You must ensure that a process exists for the production of a Declaration of Conformity.

You must ensure that the products concerned are in conformity with the type as described in the Type Examination

Certificate and that they satisfy the requirements of the Directive that apply to them.

Declarations shall be made on the basis of one or more of the following, as chosen by the Holder:

- (a) after production, in respect of an individual item of equipment, or
- (b) after production, in respect of an identifiable batch of equipment, or
- (c) in respect of equipment not yet produced but which will have the mark affixed following the checks for conformity required and for which a valid Product Verification Agreement has been made.

**Note:** The Manufacturer may vary his choice for making Declarations in respect of a particular product to suit production requirements at any given time.

#### **4.2.8 Application Agreement**

This agreement forms the contract between the BABT Certification body and you. It will normally be signed by the main contact. Where another person (e.g. A Senior Manager) within the company signs, brief details of their role related to the application should be provided with the application.

Where the manufacturer is the holder an Authorised Representative may also sign on their behalf provided the representative is either named in the Module B TEC certificate or this application includes a letter from the holder identifying them as the Authorised representative.

### **4.3 Progressing the application for a Product Verification Certificate**

#### **4.3.1 Initial receipt**

When BABT has received your application we will:

- evaluate the initial information
- send you a confirmation of your order detailing our understanding of your application
- ask you to pay an application fee
- inform you of the BABT reference number assigned to your application. This number should be quoted in all further correspondence.

#### **4.3.2 Assessment of Documentation**

BABT will review the Test report, supporting information and the lot/batch information against the agreed Sampling procedure and Test Plan.

If the allocated BABT engineer requires further information or clarification this will be addressed to the identified contact person.

When the BABT engineer has completed the assessment and is satisfied that the testing demonstrates conformity (according to the test plan) for the requested sample then the Engineer shall recommend an MED Module F Product Verification Certificate for the listed Item(s) or lot(s).

#### **Queries:**

In general, if you have a query, you should submit a written enquiry to BABT by letter, fax or e-mail for a formal response. However, engineers are available for brief technical enquiries by telephone during normal working hours

#### **Appeals**

You are entitled to make a formal appeal if you believe that you have been unjustly denied a certificate. In all cases, the decision of the appeals panel is final. Full details of the appeals procedure are given in the Certification Regulations

## **5. Testing and Test Reports**

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### **5.1.1 Selection of Test Facility**

While BABT will accept test reports from unaccredited sources we recommend the use of a formally accredited Facility as this gives more confidence in the testing and reduces the background checks which we are required to make for unaccredited testing.

Where the report is produced in an accredited test laboratory within their scope of accreditation, calibration and competence requirements shall be presumed to be met.

#### **Unaccredited Sources of testing**

Where the report has come from an unaccredited source then BABT will require information about the test methods used, any independent quality certification covering the test facility, the competence of personnel performing the testing, and the calibration status of the test equipment.

The required information may be supplied with the test reports, or supplied directly to BABT from the testing facility. Normally facilities are cleared for a given Standard for one year which may be renewed on the submission after then. Where no change has occurred and the calibration status of test equipment is in the report then renewal is a simple process.

#### **5.1.2 Testing in support of a lot**

The testing shall be in accordance to the agreed test plan and include all the elements identified in the earlier clause.

#### **5.1.3 Choice of Samples**

Where you are applying for certification for a range of models you should discuss with the facility and/or BABT how best to minimise the amount of testing required (and so limit the cost) by choosing a representative model or models from the range for the full programme of tests. However, in this situation more than others, close co-operation and detailed technical information are required in order to make the right choice. In certain cases, it may be necessary for the facility to see models other than the representative model(s), for identification and specific tests. For example, equipment which is electrically identical with a representative model but which has a different casing may require testing of the electrical, mechanical or acoustic properties of that casing.

#### **5.1.4 External Software and/or Equipment**

You should contact the test facility to see if any special software is required for the testing of your equipment. This is likely to be needed where the standards call for tests in states which are normally transient in your equipment of where special protocols are needed for your equipment to function properly.

You should also discuss with the test facility whether any external apparatus is required for the testing of your equipment. Where the external apparatus is too big to be brought to the test facility, special arrangements can be made for an on-site inspection, after full facility testing of the equipment with such sub-assemblies of the external apparatus as are available.

#### **5.1.5 Contents of Test Reports**

In general the test report shall conform to the requirements of ISO/IEC 17025 Clause 5.10.

In particular Clause 5.10.2 h, and 5.10.3.2 shall be addressed with respect to the Product verification agreement.

The report shall include the following (as appropriate)

- Summary of tests performed and where testing is spread across a number of samples which test relate to which samples
- Where parametric measurements are made the actual results shall be reported in addition to the "Pass/Fail" status of the result.
- Information on any failures found during testing with details of the consequential actions that occurred
- Indication of the lot(s) with which these results are associated
- Reference to the test plan (including issue level)

#### **5.1.6 Testing which indicates a failure to comply**

If testing of a sample (or any part of a sample) results in a failure to meet the requirements a further sample may be taken from the lot and tested.

The results of both the original testing and the testing on any additional sample must be presented to BABT. The lot shall be quarantined and may not be reworked without agreement by BABT.

The Manufacturer shall investigate the cause of failure and send a corrective action plan to BABT.

BABT will review the plan and where possible agree to an appropriate measure to enable production to resume.

Where repeated failures are reported BABT may require changes to the sampling plan or may require every item be tested.

The following extract from the MED details the formal requirements of the MED Module F in this respect.

5.3 In the case of accepted lots, the notified body must affix its identification symbol or cause it to be affixed to each product and must draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which are found not to comply.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent that lot being put on the market. In the event of frequent rejection of lots the notified body may suspend statistical verification. The manufacturer may, under the responsibility of the notified body, affix the latter's identification symbol during the manufacturing process.

## 6. Module F Certificate

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### 6.1 General

The Module F certificate is issued after a satisfactory assessment of the test data against the agreed test and sample plan and when the applicant complies with the Certification Regulations.

Certificates are issued in the name of the Applicant Company which is thereafter referred to as the holder.

Certificates also include

- the address of the holder,
- the name and address of the manufacturer and any identified Authorised Representative
- the product name
- the Marine Equipment Directive Item Types for the r Products included within the scope
- Identification of the product serial numbers/batches covered by this Certificate
- any special conditions to be complied with to maintain the validity of the certification.

The Certificate has a validity of 5 years from the time of issue

Product Verification Certificates are the property of BABT and must be returned to BABT on request.

The Manufacturer shall supply a copy of the Product Verification Certificate in response to a request for such from a flag Member State administration.

**Duplicate Certificates:** Where it is necessary to provide a signed original Certificate BABT will on request issue duplicate certificates. An appropriate fee may be charged for this service. It is advised that where known this requirement is made at the time of issue of the certificate.

The Manufacturer shall retain records of all products manufactured under the Production Verification scheme.

### 6.2 US Coast Guard Number

Where the supporting Module B Certificate is for applicable Navigation equipment and has the appropriate wording for a US Coast Guard Number then the Module F Certificate will list the full number.

If the equipment is in the list in the MRA such that BABT can issue a US Coast Guard number then if the Module B Certificate omits the number you must request this from BABT if you wish this number to be added to your Module F Certificate.

## 7. Requirements after issue of a Module F certificate

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The manufacturer shall ensure the following:

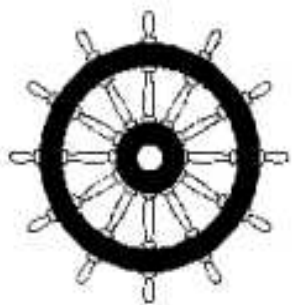
### 7.1.1 Regulatory Marking and Labelling

The Wheel Mark shall be applied only to equipment which is:

- (a) in conformity with the relevant requirements of Directive 98/96/EC, and
- (b) as identified on the relevant Module F Product Verification Certificate of Conformity.

### 7.1.2 Wheel Mark

The Wheel mark in respect of the Directive shall be applied only to equipment for which a valid Product Verification Certificate and Declaration of Conformity exists. This shall be followed by number of the Notified Body which has issued the Product Verification Certificate. The BABT notified body number is given in the example below. The characters "yy" shall be replaced by the last 2 digits of the year in which the Wheel mark was affixed to the product.



0168 yy

The formal definition and size constraint of the mark are given in MSN 1734 Annex C.

### 7.1.3 Declaration of Conformity

The Manufacturer affixing the Wheel Mark shall ensure there is a valid Declaration of Conformity (D of C) in respect to the particular product. The Declaration of Conformity should follow the general guidelines of EN ISO/IEC 17050-1. A pro forma D of C is included in Annex A of this document.

The Manufacturer shall keep a copy of the D of C for a period of 10 years after the last product has been manufactured.

D of Cs or copies of D of Cs must be made available on request to BAPT. If the Manufacturer ceases to trade then the D of Cs must be surrendered to BAPT.

## 8. Keeping your Product Verification agreement up to date

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### 8.1 General

Over the lifetime of a product and the supporting certificates, BAPT understands that it is likely that you may wish to make a number of changes

### 8.2 Technical changes to your Product

Technical Changes to your product should be addressed to the Notified Body who issued the TEC, following their process for change. Refer to BAPT 740 for the requirements where BAPT have issued the TEC.

As manufacturer you should ensure you hold a copy of the updated TEC prior to manufacturing any modified product.

Where the applicable requirements change or additional standards are applied to the product (as listed on a revised TEC) you must revise your test plan as appropriate and obtain BAPT agreement prior to producing any modified product under the agreement .

### 8.3 Changes related to details on a Product Verification Agreement or Certificate

Changes of Company Name, address, manufacturing location, or product name should be advised to BAPT by the main contact with a brief explanation of the reason behind the change.

Where the manufacturing company and address have changed BAPT reserves the right to require a sample from the first Lot produced at a new facility to be tested at an accredited test facility.

### 8.4 Other Changes

Changes to details related to the main contact, address for invoicing, and any consultant should be sent to BAPT as soon as practical.

### 8.5 Complaints and Surveillance Enquiries

Where a Product Verification Certificate holder receives a complaint related to their product they shall investigate the complaint and shall not ship further product listed on the certificate until the complaint has been fully investigated, the root cause understood and any remedial actions taken. That Product Verification Certificate and the supporting Product Verification Agreement shall be considered as suspended until this process is complete.

Where BAPT receives information which may be construed as a complaint related to the conformity of any product covered by a Module F agreement the received information will be passed to the Product Verification Certificate of Conformity holder to investigate and progress as above, with the additional requirement that BAPT be informed of the outcome before the Holder makes any further applications for a Product Verification Certificate for that product.

BAPT will progress Surveillance requests from Flag states in a similar manner to Complaints received but will forward the outcome to the requesting Flag state, and copy the UK Maritime and Coastguard Agency.

## **Annex A Pro forma Declaration of Conformity**

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We,

.....  
*(manufacturer's name)*

of

.....  
.....  
.....  
*(address)*

declare under our sole responsibility that the product

.....  
.....  
.....  
*(detailed description of product including name, type, model and supplementary information such as lot, batch or serial number, sources and number of items)*

to which this declaration relates, is in conformity with the following standards and/or other normative documents.

Type Examination Certificate Number

.....  
*(or Replace Type with Unit for Unit Examinations)*

Standards:

.....  
.....  
.....  
We hereby declare that the above named product is in conformity to all the relevant requirements of Directive 96/98/EC.

The following Notified Body is responsible for the product surveillance

Notified Body Number :

.....  
.....  
.....  
*(name and address of Notified Body)*

The technical documentation relevant to the above equipment will be held at:

.....  
.....  
.....  
*(name and address of EU representative)*

.....  
*(name)*

.....  
*(title)*

.....  
*(signature of authorised person)*

.....  
*(date)*