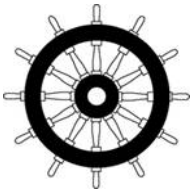
Approval as per EU Marine Equipment Directive (MED)



Guidance for Equipment Manufacturers

IRCLASS
Indian Register of Shipping

Purpose of the document

The existing practices of product certification by Indian Register of Shipping is through an impartial scheme for Type Approval which ensures that the products are manufactured under quality control system to continuously meet all the requirements of the product specification.

Every classification society extends such services of product certification to ensure that the products which are intended to be used onboard vessel are as per their rules or recognised standards. However, the agencies like EU and USCG have specific requirements for the products which are additionally to be complied for their acceptance. IR Class has embarked on a process to get EU recognition as notified body in India which can render services to Indian manufacturers enabling production to quality for global acceptance of their products.

This document is prepared for guidance to the manufacturers particularly within India who may seek for our services once we obtain the EU notified body status. The generic guidelines are enumerated in the succeeding paragraphs is to be read in conjunction with the Type Approval scheme of IRS which is also available on our website www.irclass.org

1. Introduction to MED

European Union publishes various Directives in several fields to allow free movement of goods within the European Union.

The Council Directive 2014/90/EU (repealing 96/98/EC) pertains to marine equipment (hereinafter referred to as the "MED"). Materials and equipment, covered by this MED and intended to be used on board ships and which are found in compliance with the requirements of the MED may be affixed with the "Wheel Mark" together with the unique ID number of the certifying Notified Body and shall be accompanied by an EC Declaration of Conformity issued by the respective manufacturers.

Materials and equipment to be installed on board ships registered in the EU countries and EFTA countries shall mandatorily meet the requirements of the MED. Wheel marked equipments are also accepted by several other Flag Administrations. This enables free movement of your products in EU and many other countries.

2. Definitions

2.1 Conformity**:** The fulfillment by a product or group of products, of all requirements specified.

2.2 Conformity Assessment: means the process carried out by the notified bodies demonstrating whether the marine equipment complies with the requirements of MED

2.3 Notified Body: means an organization designated by the competent National Administration of a EU Member State

3. Approval Procedure

3.1 Application for Type Approval

The manufacturer intending to apply for certification as per EU MED is to apply in writing to IRS Head Office or the nearest Survey Station. The application form "SRF (EU MED)"can be downloaded from IRCLASS website. The list of documents to be submitted are stated in the form.

3.2 Conformity Assessment Procedures as per various Modules

Manufacturer is to ensure that the product which he intends to get certified is listed in Annex A.1 of the MED. The conformity is generally demonstrated in 2 steps –

- Product design review and testing as per applicable standard
- Assessment of Quality systems

The following conformity assessment procedures (MED) are described in MED:

Module B – EC Type Examination

Module D - Production Quality Assurance

Module E - Product Quality Assurance

Module F - Product verification

Module G - Unit verification

Referring to Annex A.1 of the MED, manufacturer can choose from the combination of assessment procedures (modules) applicable for the product type. (For e.g, Module B+D or Module B+D, or Module B+F)

Brief description of the modules is given below. For detailed description refer Annex B of the MED.

Module B – EC Type Examination:

IRS will carry out design appraisal, document review and witness testing of the product to ascertain if the product complies with the international standards as described in Annex A.1 of the MED. An "EC Type Examination Certificate" will be issued by IRS on successful completion of design assessment and testing. Testing carried out NABL accredited laboratories and not witnessed by IRS Surveyor may be considered with prior approval from IRS.

For most products, a Module B Certificate is mandatory and it must be used in combination with one of the Modules for Quality System Assessment i.e. Module D, E or F.

Module D - Production Quality Assurance:

This involves assessment of Quality system of manufacturer to ensure that the complete production process results in equipment meeting the standard of the prototype to which

the EC Type Examination Certificate was issued. This module requires manufacturer's quality system to have in-process testing as well as testing of final product.

Module E – Product Quality Assurance:

This also involves assessment of Quality system of manufacturer to ensure that the complete production process results in equipment meeting the standard of the prototype to which the EC Type Examination Certificate was issued. This module requires manufacturer's quality system to have post production inspection/testing regime.

Module D or E is primarily for the equipment which are mass produced. Upon completion of module D or E, Certificate of Conformity stating the module will be issued.

Module F – Product Verification:

This involves equipment manufactured in smaller batches or lots. Manufacturer is to schedule inspection in advance of the intended production. Each product type of the same item designation is to have valid EC Type Examination Certificate. IRS surveyor would examine the batches and would select samples for testing as per applicable standards/codes etc. Manufacturer's records of production will be verified to ensure conformity with the prototype. Certificate of Conformity for Module F will indicate the batch and serial numbers.

Module G – Unit Verification:

This module involves prototype tests and production tests on every individual product as per applicable standards/codes etc. Very few types of equipment come under purview of this module. After testing, Certificate of Conformity for Module – G is issued to an individual item or a small batch of items. The manufacturer can then affix the 'mark' (wheelmark) to the concerned products and issue "Declaration of Conformity".

4. Certification

After satisfactory completion of the necessary reviews, inspections and auditing, IRS will issue the following certificates:

- EC Type Examination Certificate after completion of the EC type-examination (Module B)
- EC Certificate of Conformity after completion of the Production-Quality Assurance (Module D), Product-Quality Assurance (Module E), Product Verification (Module F) or Unit Verification (Module G).

Validity of EC Type Examination Certificate (Module B), EC Certificate of Conformity (for Modules D & E) is for 5 years

5. Mark of Conformity

The Wheelmark, also called the mark of conformity can be affixed to the product when the applicable modules have been satisfactorily completed and associated certificates as mentioned in paragraph 4 have been issued. The format for the Wheelmark is given in the MED. The mark consists of a ships wheel together with the identification number of the certifying Notified Body (in this case the number will be provided by IRS) along with the last 2 digits of the year of manufacture.

6. Declaration of Conformity

Manufacturer's "Declaration of Conformity" is a document which describes the product and declares that the product concerned conform to type as described in the EC type-examination certificate and satisfy the requirements of the relevant international instruments. The Declaration of Conformity is to be supplied with the product and is to be kept onboard. The manufacturer or his authorized representative in EU must keep a copy of the declaration of conformity for at least 10 years after the last product has been manufactured.

Although there is no fixed format for the Declaration of Conformity, a sample format available on IRS website may be referred.

7. Periodical Surveillance

To ensure that the manufacturer maintains and applies the quality system, an assessment of the manufacturer's quality assurance system, production process and production & testing facilities is done periodically. Surveillance and endorsement would be applicable for marine equipment having issued with certificate under Module D or Module E. The periodicity of endorsement is annual. Periodical endorsement is to be carried out on or before the due date. However in exceptional cases, with a written permission a grace of period of 3 months after due date is provided to complete the periodical audit for that particular year.

8. Manufacturer's Responsibilities

i. By affixing the wheel mark, manufacturers shall take on responsibility for guaranteeing that the marine equipment to which the mark is affixed has been designed and manufactured in accordance with the applicable technical specifications and standards.

ii. Each product supplied is in strict conformity with that certified by IRS. Changes in marine equipment design or characteristics and changes in the requirements in the international instruments, on the basis of which conformity of marine equipment is declared, shall be taken into account and communicated to IRS. When necessary, manufacturers shall have a new conformity assessment carried out.

iii. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does

not allow it, that the required information is provided on the packaging or in a document accompanying the product or both, as appropriate.

iv. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate. The address must indicate a single point at which the manufacturer can be contacted.

v. Each product supplied is provided with adequate protection and preservation, to maintain conformity with the IRS certification, until it reaches the purchaser.

vi. Each product supplied is provided with appropriate instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product, its installation or with respect to its purpose.

vii. Manufacturers shall draw up the required technical documentation and have the applicable conformity assessment procedures carried out.

viii. Manufacturers shall keep the technical documentation and the Declaration of Conformity 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.

ix. The manufacturer must not mislead purchasers concerning IRS type approval by the claiming of performance or purpose of products not covered by the certification.

x. The manufacturer shall maintain a record of all complaints and corresponding corrective actions taken to each product certified. Such records must be available for IRS's review on request.

xi. Manufacturers who consider or have reason to believe that a product to which they have affixed the wheel mark is not in conformity with the applicable design, construction and performance requirements and with the testing standards, shall immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or to recall it, if appropriate. In addition, where the product presents a risk, manufacturers shall immediately inform IRS and the competent national authorities of the Member States, giving details, in particular, of the non-compliance and of any corrective measures taken.

xii. Manufacturers shall, further to a reasoned request from a competent authority, promptly provide it with all the information and documentation

9. Amendment to the certificate

Request for amendment(s) to the existing certificate within the validity period may be considered under following cases:

a) Change in Name of the Company

b) Change in registered address of company

c) Change in address of manufacturing location

d) Change in Trade name of the product

e) Amendments in applicable standards/codes etc.

f) Any other change not indicated above

Manufacturer is to submit Form SRF(EU MED)Rev.00 to H.O. indicating clearly the scope as "Revision of certificate". Details of changes requested and supporting documents (where applicable) are to be submitted. Extent of testing, inspection and audit will be communicated by IRS based on the nature of reason for amendment.

Validity of the certificate will be kept unchanged from the original certificate.

10. Suspension or Withdrawal of the certificate:

A certificate would be withdrawn if:

a) Any design and/or construction changes are made to a certified marine equipment which are deemed to adversely affect the descriptive or performance provisions under which certification was granted;

b) Safety or any other feature of a certified marine equipment is found to be unsatisfactory in service;

c) Improper use is made of the certificate or the wheelmark or of IRS's name, in marketing the product

d) Due settlement of fees for IRS's services associated with the type approval certificate is not completed.

e) The manufacturer moves from the address stipulated on the certificate, without informing IRS in writing.

f) the marine equipment manufacturer does not wish to renew the certification;

g) the marine equipment is no longer manufactured

If IRS considers that a certificate issued under EU MED Certification process is to be withdrawn, the manufacturer will be informed in writing and given the opportunity to take appropriate corrective action or give notice of appeal.

11. Renewal of Certificates:

A type approval certificate may be renewed for a further period of 5 years, at the manufacturer's request, by the issue of a new certificate. Certificate renewal is applicable

for the marine equipments which have been issued with certificate under Module B, Module D and Module E. An audit of manufacturing location is to be carried out to review manufacturer's quality assurance system, production process and production & testing facilities to ensure that the materials, manufacturing and production controls continue to ensure the conformity of the product and to ensure that there are no changes made to the product and processes. IRS will communicate if there are any additional testing requirements depending on any changes to the product, revisions in the testing procedure / acceptance criteria in applicable standards/codes etc. affecting the approval.

12. Display of Certificates:

Certificate copies will be displayed on IRS website and the product details will be listed on MarED website.

Fig: Achieving MED Certification with IRS