Conformity Assessment procedures for the Marine Equipment Scheme

RD_040, Issue 23

This document describes the conformity assessment procedures and requirements marine communication, navigation, fire protection and lifesaving equipment have to comply with when placed on the European market.

Revision record sheet

NOTE: The person who initiated the document or modified the document is responsible for maintaining this record sheet

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1 Introduction

1.1 About Kiwa

Kiwa Nederland B.V. (unit Wireless & EMC), hereinafter to be referred to as Kiwa) is a third party test laboratory and third party certification body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited the unit wireless & EMC (legal entity of Kiwa NL B.V.) to ISO/IEC 17025 (laboratory) and NEN-EN-ISO/IEC 17065 (product certification).

More information about Kiwa Nederland (unit Wireless & EMC), is available in *RD_0063.*

1.2 About this document

This document lays down the procedures for the Economic operators (manufacturers, authorized representatives, importers and distributors) who want to apply for the services of Kiwa in order to place and making available of their marine communication, navigation, fire protection or lifesaving equipment on the market of the European Union. This with a view to place the equipment on board an EU ship

Described are the conformity assessment procedures that have to be followed before these products may be placed on the market and how to act when modifications to such products are made. The added value of the services of Kiwa is given. When the service of a Notified Body is needed a description is given of the implementation of these services by Kiwa. The Notified Body services are derived from the conformity assessment procedures as defined in the Maritime Equipment Directive (MED) 2014/90/EU.

Furthermore this document gives information how to act when modifications to equipment are made. It also describes specific conditions, such as markings on the products, declarations to be drawn up, etc., which economic operators will have to deal with when using a conformity assessment procedure with the involvement of a Notified Body.

1.3 Overview of the services of Kiwa

1.3.1 Introduction of services

Kiwa offers four groups of services: Information, Certification, Test and Notified Body services.

The Information services of Kiwa as far as related to the MED are:
- MED package (Project guidance)
- Storage of Technical documentation
- Compilation of a Technical File

The Test services of Kiwa relevant for the MED are:
- Electrical Safety
- EMC
- Radio
- Maritime international instruments (IMO, ITU, ISO, IEC, CEN, CENELEC, ETSI)

The Certification services of Kiwa relevant for the MED are:
- Module B: EC type-examination
- Module D: Production-quality assurance
- Module E: Product-quality assurance
- Module F: Product verification
- Module G: Unit verification

The Notified Body services of Kiwa as defined by the MED are:
- Surveillance (under Module D & E)

1.3.2 The MED Package (project guidance)

The MED Package (project guidance) is a service to assist the manufacturer or his authorized representative in his objective to meet all the requirements of the MED for placing his product on the EU market. This is done by means of supplying information to the manufacturer. The complete process is managed by Kiwa and finally the manufacturer has to sign the documents (declarations) prepared by Kiwa.

Elements of the MED Package are:

- List containing all related mandatory and voluntary standards
- Marking/label
- Additions to manual
- Package instructions
- Proposal on declarations (need to be printed on company letter head paper!)
- Archiving of the Technical Documentation by Kiwa (as long as required by the MED)
- Supplying information on current and changing regulations
- Granting access to surveillance authorities
- Delivering maintenance of the Technical Documentation in case of additions / modifications

Production Control and certification of a Quality Management System are outside the scope of the MED Package. So are the costs involved with Testing and Notified Body activities.

1.3.3 Storage of technical documentation

The procedures of Kiwa regarding the archiving of files, which are part of the accredited quality system of Kiwa, are applicable for this storage of Technical Documentation.

1.3.4 Compilation of a Technical File

This is explained in Chapter 6.

1.3.5 Testing Services

Kiwa is accredited by the Dutch accreditation council (RvA) according ISO 17025. The accredited laboratory is capable of testing the following relevant areas for maritime equipment:

- Electrical Safety
- EMC
- Radio
- Maritime international instruments (IMO, ITU, ISO, IEC, CEN, CENELEC, ETSI)

1.3.6 Certification Services

Kiwa is accredited by the Dutch accreditation council (RvA) according ISO 17065 for product certification under number C002. The scope of accreditation also lists this maritime equipment scheme document, RD_040.

Kiwa is designated as Notified Body for the MED (2014/90/EU). The Notified Body number of Kiwa is 0063. This designation can be verified in the NANDO database on the European Commission website: http://ec.europa.eu/growth/tools-databases/nando/

The designation covers the Modules B,D,E,F and G:

- Module B: EC type-examination
- Module D: Production-quality assurance
- Module E: Product-quality assurance
- Module F: Product verification
- Module G: Unit verification

EC Type-examination
Kiwa Notified Body assesses the design of a representative specimen of the production envisaged, possibly by means of tests generally performed by an accredited test laboratory.

Production quality assurance
Kiwa Notified Body assesses whether the manufacturer's production process is of a sufficiently high standard to guarantee that the products satisfy the (statutory) requirements (ISO 9001 like quality systems).

Product quality assurance
A Notified Body assesses the manufacturer's quality system to ensure that appropriate tests are performed on each product to guarantee that the products satisfy the (statutory) requirements (ISO 9001 like quality systems).

Product verification
A Notified Body assesses the verification method of the manufacturer either by means of examination and testing of each product or by means of statistical verification.

Unit verification
The Notified Body subjects each product to a type-examination.

1.3.7 Surveillance (Notified body service under module D and E)

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. This is a responsibility in the name of Kiwa as a Notified Body. Kiwa shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. This is not to be confused with Market surveillance performed by market surveillance authorities, which is described in Chapter 2.2.

Kiwa can be involved in market surveillance to trace if non-compliant radio equipment is available on the market. If so, Kiwa will inform and share this information with other notified bodies. Kiwa, as a Notified Body can perform market surveillance tests in its own test lab and has to inform the national market surveillance authority: Inspectie Leefomgeving en transport (part of Ministery of Infrastructure and Environment) if there is any non-compliance.

1.4 Flow diagram of services

For the follow diagram of all Kiwa MED related services see figure 1.

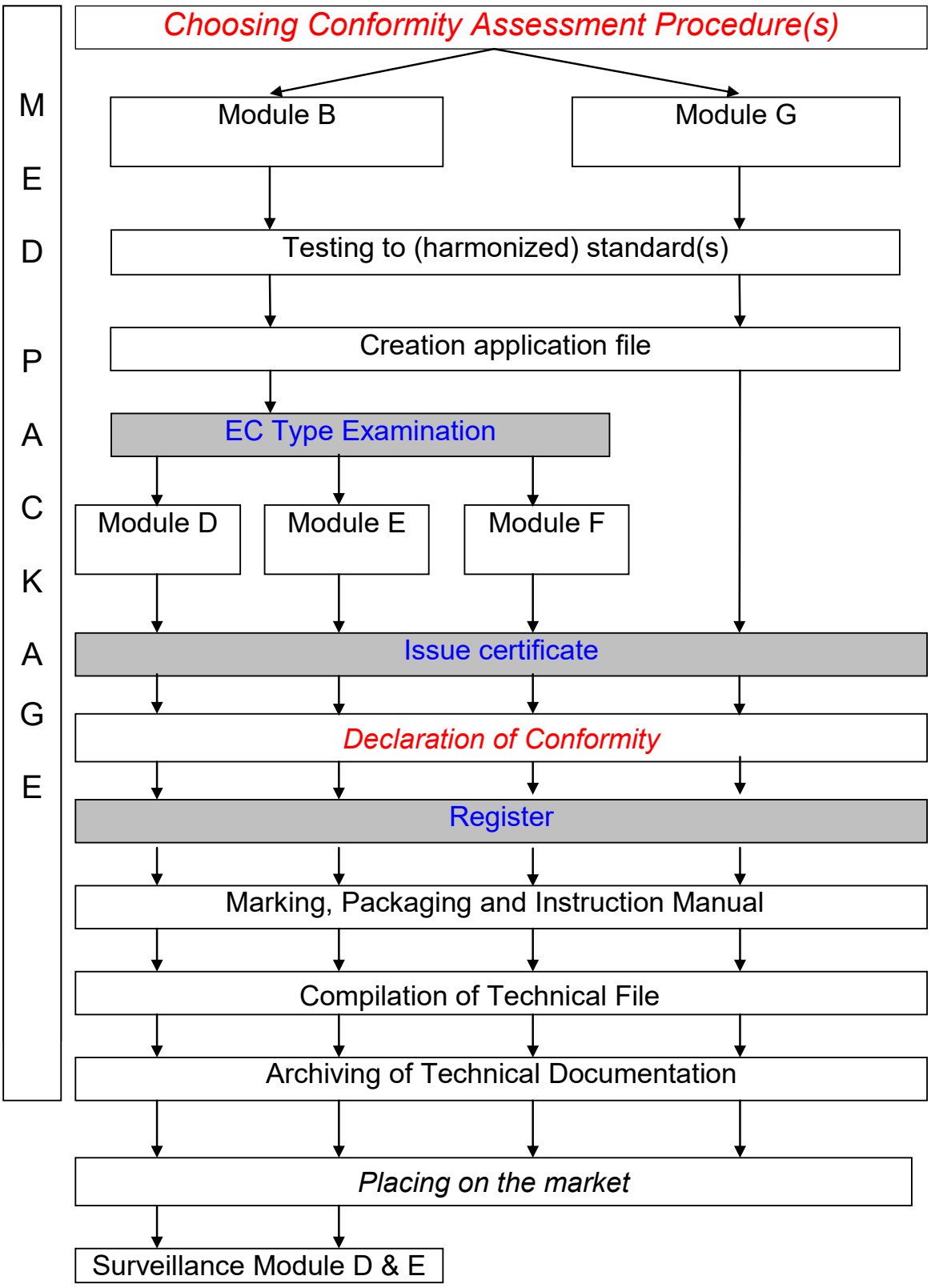

Figure 1: Flow diagram of services

Some clarification:
Some activities are the direct responsibility of the manufacturer: they cannot be subcontracted or outsourced to third parties. In the flow diagram these activities are described with Italic letters and in red (*Choosing Conformity Assessment Procedure, Declaration of Conformity*). The *Creation of Technical Documentation* is an activity of the manufacturer. This technical documentation will be bundled into a Technical file.
The activities mentioned in grey boxes with blue letters have to be done by a MED Notified Body, like Kiwa. All the other activities can be fulfilled by the manufacturer or a third party (importer, authorized representative, distributor). Kiwa -as a third party- can supply services for all these activities, except *Placing on the market*.
Testing can be performed by Kiwa under accreditation (ISO 17025). In some cases (dependent of the availability or transportability of test equipment) the tests can also be performed on location.

2 European regulations

2.1 Introduction

The policy objectives of the first harmonization of EU Regulations and directives, concentrating on the elimination of trade barriers and on the free movement of goods for the development of a single market, are now being balanced out by a comprehensive policy geared to ensuring that only safe and compliant products find their way to the market, in such a manner that honest economic operators can benefit from a level playing field, thus promoting at the same time an effective protection of the EU consumer and a competitive single EU market.

Policy orientations and legislative techniques alike have profoundly changed in the last 35 years of European integration, especially in the area of the free movement of goods, contributing to make this area of activity a symbol of the success of the Single Market today.

Historically, EU legislation for goods has progressed through four main phases:

- the traditional approach or 'Old Approach' with detailed texts containing all the necessary technical and administrative requirements;
- the development of the 'New Approach' in 1985, which restricted the contents of legislation to the "essential requirements" leaving the technical details to European harmonised standards. This in turn led to the development of the European standardisation policy in support of this legislation;
- the development of the conformity assessment instruments made necessary by the implementation of the various Union harmonisation texts, both 'new approach' and 'old approach', leading to the ‘Global approach” as described in Council Decision 93/465/EEC of 22 July 1993;
- the 'New Legislative Framework'[1] adopted in July 2008, which builds on the 'New Approach' and completes the overall legislative framework with all the necessary elements for effective conformity assessment, accreditation and market surveillance including the control of products from third countries.

2.2 The New Legislative Framework (NLF)

This is a general framework of a horizontal nature for future legislation harmonizing the conditions for the marketing of products and a reference text for existing legislation.

In the Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products[2], and repealing Council Decision 93/465/EEC provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures from which the legislator can select as appropriate. The Annex I of this document shows the different responsibilities of manufactures (Article R1), authorized representatives (Article R2), Importers (Article R4) and distributors (Article R5).

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[3] and repealing Regulation (EEC) No 339/93. This regulation lays down rules on the organization and operation of accreditation of conformity assessment bodies performing conformity assessment activities. It also provides a framework for the market surveillance of products to ensure that those products fulfill requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security and provides a framework for controls on products from third countries. This Regulation lays down the general principles of the CE marking.

Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. The aim of this Regulation is to

1 Regulation 765/2008 and Decision 768/2008/EC
2 OJ L 218, 13.8.2008, p. 82
3 OJ L 218, 13.8.2008, p. 30

strengthen the functioning of the internal market by improving the free movement of goods. This Regulation lays down the rules and procedures to be followed by the competent authorities of a Member State when taking or intending to take a decision, which would hinder the free movement of a product lawfully marketed in another Member State. It also provides for the establishment of Product Contact Points in the Member States to contribute to the achievement of the aim of this Regulation.

2.3 NLF and MED

The MED should take into account of the horizontal legal framework for the marketing of products in the internal market, established by Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products as well as by Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

2.3.1 Economic operators:

Four economic operators are defined: Manufactures, Authorized representatives Importers and Distributors. The economic operators have different obligations (a summary is given in table1), which are in line with the NLF (Decision No 768/2008/EC). Articles 12 – 14 of the MED mention the obligations of the economic operators.

A new requirement of the MED is the mandate to provide more contact information for the economic operators. EU Member States will require the economic operators to provide a physical location postal addresses, in order to facilitate better communications between the member states, market surveillance authorities, economic operators, and consumers. The equipment must show the product identification numbers and contact information for the responsible parties. A contact name and details must be supplied with each device, and also placed on the device or in documentation if it is a small device. Importers must show similar information on the equipment or on the packaging; the supply chain must accept the legal responsibility for providing valid contact information.
Importers will be seen as manufacturers when placing products under their own name, brand name or changing the equipment.

Economic operators shall, on request, identify the following to the market surveillance authorities:

- Any economic operator who has supplied them with a product.
- Any economic operator to whom they supplied a product.

Economic operators shall be able to present this information for 10 years after they have been supplied with the product and for 10 years after they have supplied the product.

More summarising information about the obligations of Economic Operators can be found in table 1.

	Manufacturer	Authorised representative	Importer	Distributor
Design and manufactured in accordance with the technical specifications and standards in accordance Article 35(2)	YES			
Placing on the market only when comply to essential requirements	YES		YES	YES
Carry out the relevant conformity assessment procedure	YES, or have it carried out		Ensure it is carried out	
Technical Documentation	Issue and 10 years filling and providing	Yes 10 years filling and providing	Ensure it is drawn up and 10 years filling and providing	Verify
Declaration of Conformity	Issue and 10 years filing	10 years filling and providing	10 years filling and providing	Verify
Wheel mark	Affix		Ensure	Verify
Type, serial number, id	On equipment (or package or documentation for very small equipment)		Ensure	Verify
Name,tradename or registered trade mark postal address	On equipment (or package or documentation for very small equipment)		Check details + add postal importer.	Verify details manuf. + importer
Manual, installation instruction and user restrictions.	Issue + add to equipment.		Ensure	Verify
Continuous compliance of series production	Have a procedure to ensure series production in compliance			
Corrective actions on Non-compliances	Corrective measures		Corrective measures	Corrective measures
Inform National authorities when risk.	YES		Yes+ manufactur er	Yes+ manufactur er
Cooperation National authorities	YES	YES	YES	YES
Cooperation National Authorities for market surveillance	YES + 10year	YES + 10year	YES + 10year	YES + 10year

Table 1: Economic operators and different aspects of the certification process

2.4 Implementation of the MED

The general objectives and main instruments of the MED have not changed.

Member States shall adopt and publish, by 18 September 2016 at the latest, the laws, regulations and administrative provisions necessary to comply with the MED 2014/90/EU. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 18 September 2016.

Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by the MED.

2.4.1 Differences between 2014/90/EU and 96/98/EC

The most important changes of the new MED compared to the old MED are:

- General alignment with the NLF
- The use of an Electronic Tag (article 11 of MED). As implemented via delegated acts.
- Simplified system for transposition of EU legislation
- Notification has been strengthened
- Strengthened control on Notified bodies (more requirements and more inspection)
- Enhanced means of and information to market surveillance authorities
- Definition of economical operators
- The DoC should be kept on board the ship and be written in English and in the language of the applicable flag member state
- Module H has been removed
- Notified bodies must be active in participation sectoral group (NB group: MARED)
- Register of issued certificates in a database has been formalized (article 35.4)
- Testing laboratories must meet ISO/IEC 17025 requirements (to be ensured by the conformity assessment body)

2.5 Scope of MED

The objective of the MED is to enhance safety at sea and to prevent marine pollution through the uniform application of the relevant international instruments relating to marine equipment to be placed on board EU ships, and to ensure the free movement of such equipment within the Union.

The MED shall apply to equipment placed or to be placed on board an EU ship and for which the approval of the flag State administration is required by the international instruments, regardless of whether the ship is situated in the Union at the time when it is fitted with the equipment.

Notwithstanding the fact that the equipment may also fall within the scope of instruments of Union law other than the MED, that equipment shall, for the purpose set out in the objective of the MED, be subject only to the MED.

2.6 Requirements for marine equipment

Marine equipment within the scope of the MED must meet the following requirements:

1. Marine equipment that is placed on board an EU ship on or after the date referred to in the second subparagraph of Article 39(1) of the MED shall meet the design, construction and performance requirements of the international instruments as applicable at the time when that equipment is placed on board.

2. Compliance of marine equipment with the requirements referred to in the first item above, shall be demonstrated solely in accordance with the testing standards and by means of the conformity assessment procedures referred to in Article 15 of the MED.

3. The international instruments shall apply, without prejudice to the conformity checking procedure set out in Article 5 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council[4] .

4. The requirements and standards referred to in items 1 and 2 above, shall be implemented in a uniform manner, in accordance with Article 35(2) of the MED.

4 Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) (OJ L 324, 29.11.2002, p. 1.).

2.7 Standards and international conventions

The Marine Equipment Directive prescribes that marine equipment shall comply with specific requirements of the international conventions and of the relevant resolutions and circulars of the International Maritime Organization (IMO). Compliance with given test standards is therefore mandatory.

According to article 35 of the MED, each item of marine equipment for which the approval of the flag State administration is required by the international conventions, the Commission shall indicate by means of implementing act (Implementing Regulation) the respective design, construction and performance requirements and the testing standards provided for in the international instruments. When adopting those acts, the Commission shall explicitly indicate the dates from which those requirements and testing standards are to apply, including the dates for placing on the market and placing on board, in accordance with the international instruments, and taking into consideration timeframes for ship-building. The Commission may also specify the common criteria and detailed procedures for their application.

The Commission shall, by means of implementing acts, indicate the respective design, construction and performance requirements newly provided for in the international instruments and which apply to equipment already placed on board, in order to ensure that equipment placed on board EU ships complies with the international instruments.

For that equipment for which both IEC and ETSI standards are given, the manufacturer has a freedom of choice to select which of them he will use to show compliance, in other words the IEC standards may be used or the ETSI standards. Both sets of standards are regarded equivalent.

2.8 Register

The Commission shall set up and maintain a database containing at least the following information:

(a) the list and essential details of the conformity certificates issued pursuant to the MED, as provided by the notified bodies;

(b) the list and essential details of the declarations of conformity issued pursuant to the MED, as provided by the manufacturers;

(c) an up-to-date list of the applicable international instruments, and of the requirements and testing standards applicable by virtue of Article 4(4) of the MED;

(d) the list and full text of the criteria and procedures referred to in paragraph 2 of article 35 of the MED;

(e) the requirements and conditions for electronic tagging referred to in Article 11 of the MED, when applicable;

(f) any other useful information with a view to facilitating correct implementation of the MED by the Member States, the notified bodies and the economic operators.

That database shall be made accessible to the Member States. It shall also be made available to the public for information purposes only.

2.9 Conformity assessment

Conformity assessment means the process of demonstrating whether the requirements relating to certain equipment have been fulfilled.

The manufacturer, or its authorized representative shall perform a conformity assessment, through a notified body, of the marine equipment before any piece of marine equipment may be placed on board of an EU ship. In order to be legally used on board of an EU ship, equipment must comply with the requirements as mentioned in Article 4 of the MED.

In Article 15 of the MED the conformity assessment procedures are explained. The manufacturer can choose to carry out through a notified body the following options :

- Module B + Module D
- Module B + Module E
- Module B + Module F
- Module G

The conformity assessment shall take into account all intended operating conditions. The assessment shall also take into account the reasonably foreseeable conditions. Where the equipment is capable of taking different configurations, the conformity assessment shall confirm whether the equipment meets the requirements in all possible configurations.

2.10 Bodies involved in the conformity assessment

A conformity assessment body is the body that performs conformity assessment activities. Conformity assessment bodies can get notified by their national notifying authority, according article 17 of the MED. To get notified the conformity assessment body needs to fulfil the requirements laid down in annex III of the MED. The conformity assessment body is then notified to the European Commission and the other Member States of the EEA and thereby acquires the status of 'Notified Body'. After successful notification a conformity assessment body will have its own Notified Body identification number assigned by the Commission.

A Notified Body is a third party who is authorised to perform the tasks relating to conformity assessment as specified in any European Directive they are notified for. Hence it is possible a single Notified Body is notified for multiple fields of profession.
The Notified Bodies designated by member state notifying authorities have to satisfy certain criteria regarding proficiency, independence, impartiality, etc. In this respect, standards like ISO/IEC 17020, ISO/IEC 17025, ISO/IEC 17065 are particularly important.

Although responsibility for conformity assessment lies entirely with the manufacturer, the MED makes it obligatory to enlist the services of a notified body for all conformity assessment modules applied. The bodies involved in the conformity assessment have their own tasks and responsibilities.

Regarding to the MED the following bodies are defined:

(1) Notified body
(2) Testing laboratory

2.10.1 Notified Body

A list of Notified Bodies notified under the MED by the Member States to the European Commission can be found on Nando under the following link:
http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main
Under number 0063 Kiwa is listed.
Kiwa is a MED Product Certification Body, who can be involved in conformity assessment procedures of modules B, D, E, F or G.

2.10.2 Testing Laboratory

A test laboratory should capable to perform tests, which are part of the conformity assessment procedures. The laboratory can be chosen by the manufacturer. The test laboratory can be the own appropriate laboratory of the manufacturer, or any other test laboratory on his behalf and under his responsibility.

A test laboratory can be accredited on the basis of an assessment in accordance with a quality standard, i.e. IEC/ISO 17025. There is no legal obligation to use an accredited laboratory. However according annex III, the conformity assessment bodies shall ensure that testing laboratories used for conformity assessment purposes meet the requirements of standard EN IEC/ISO 17025:2017. The test laboratory of Kiwa is accredited to IEC/ISO 17025.

2.11 Notified body obligations

Regarding article 23 & 24 of the MED there are some operational and information obligations of notified bodies. These obligations will be discussed in this section.

2.11.1 Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments or have them carried out in accordance with the procedures provided for in Article 15 of the MED.

2. Where a notified body finds that the obligations laid down in Article 12 have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures without delay and shall not issue a conformity certificate.

3. Where, in the course of monitoring conformity following the issue of a conformity certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures without delay and shall suspend or withdraw the certificate if necessary. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw the certificate, as appropriate.

2.11.2 Obligation of notified bodies to provide information

1. Notified bodies shall inform the notifying authority of the following:
   (a) any refusal, restriction, suspension or withdrawal of an EC type-examination certificate;
   (b) any circumstances affecting the scope of or conditions for notification;
   (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
   (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting

2. Notified bodies shall provide the Commission and the Member States, on request, with relevant information concerning issues relating to negative and positive conformity assessment results. Notified bodies shall provide the other notified bodies carrying out conformity assessment activities covering the same products with information concerning negative and, on request, positive conformity assessment results.

3. Notified bodies shall inform the minister of the following:
   Conformity assessment activities performed by subcontracting.

2.12 Coordination of notified bodies: MarED

According article 34 of the MED notified bodies are obliged to take part in sectoral notified body group. For marine equipment the applicable notified body group is the MarED

Kiwa has joined the MarED and has actively contributed in this group since its founding. Kiwa will continue contribution in the MarED in future.

Kiwa follows the approved recommendations as officially issued by MarED.

3 Conformity assessment procedures

3.1 Overview of routes to conformity

The MED gives four alternative routes that can be used to show conformity with the EU regulations. The manufacturer, or its authorized representative has to choose from the following options:

- EC type-examination (Module B) + Production quality assurance (Module D)
- EC type-examination (Module B) + Product quality assurance (Module E)
- EC type-examination (Module B) + Product verification (Module F),
- EC unit verification (Module G)

The first three procedures comprise two sub-procedures, one (the EC type-examination) regarding the design of the product and one regarding the production. In each of these cases both sub-procedures must be concluded before a product may be marketed. A flow diagram how a manufacturer can make the choice is shown in Figure 2.

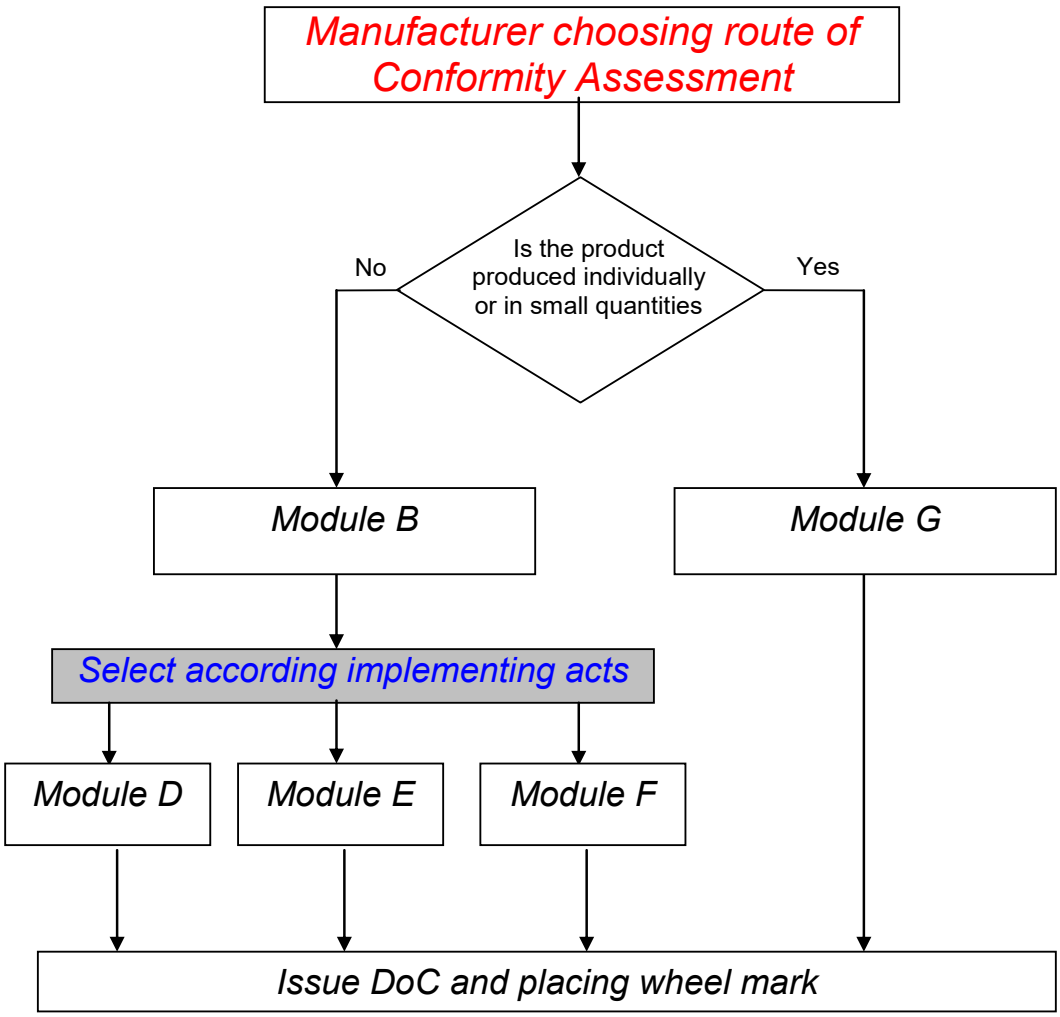

Figure 2: Flow diagram for choosing the conformity assessment procedures

To demonstrate compliance of the marine equipment with the requirements set out in Article 4 of the MED, one out of the four routes has to be chosen by the manufacturer. A note should be made that for certain types of marine equipment, the allowed combinations to be selected are limited by the implementing acts adopted by the Commission (as referred to in Article 35 of the MED). The full text of the conformity assessment modules can be found in the annex II of the MED.

3.2 The Telefication Approach and the MED

The NLF which is the basis for almost all the European Directives with respect to product compliance describes procedures for the assessment of products. Each procedure comprises both the design phase and production phase of a product. The procedures differ in nature and are applied according to the potential risk associated with a non-compliance product. For instance, emergency beacons (EPIRB) have to satisfy much more stringent assessment requirements than toy trains.

Depending on the risk associated with a particular product, Directives specify in which cases need which kind of conformity assessment procedure. For MED all possible conformity assessment procedures require involvement of a Notified body.

Kiwa as a Notified Body has developed the Kiwa Approach, which is a superset of the MED requirements. The Kiwa approach can also be used for approval scheme outside Europe and for voluntary product certification.

The Notified Body services of Kiwa were earlier briefly described in the chapter 1.
The Kiwa approach to conformity assessment comprises of testing, certification services and other notified body services, which will be described in relation to the different modules of conformity assessment in the next sections.

3.3 EC type-examination (Module B)

Kiwa examines the technical documentation and supporting evidence to assess compliance with the provisions of the relevant international instruments, resolutions, circulars and test standards applicable to the marine equipment. Afterwards Kiwa writes an evaluation report. Only if the equipment is found to be compliant, the notified body issues an “EC type-examination Certificate”. See chapter 4 how to apply for an “EC type-examination Certificate” and how Kiwa issues the EC type-examination certificate.

The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly (see Chapter 5 for more details).

The manufacturer must inform Kiwa of all modifications to the product that may affect compliance with the essential requirements or the conditions for validity of the EC-type examination certificate. Chapter 5 describes how a manufacturer can apply with Kiwa for these kind of changes.

Kiwa shall inform its notifying authority concerning the EC type-examination certificates and/or any additions thereto which it has issued or withdrawn.
Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by Kiwa. Kiwa shall keep a copy of the EC type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for at least 10 years after the marine equipment has been assessed or until the expiry of the validity of that certificate.

3.4 Production quality assurance (Module D)

This procedure is in particular interesting if high or mass production volumes are made.

The *Production quality assurance* procedure relates to the production phase of a product. In this case the quality assurance of the production process is assessed by Kiwa to verify that the manufacturer is capable of meeting the provisions of the relevant international instruments. Application for this procedure requires that the manufacturer has implemented a quality system that assures a controlled level for production, final product inspection and testing.

Kiwa performs an examination of the quality system of the manufacturer. A *Production quality assurance certificate* will be issued when the quality system satisfies the requirements as laid down in Annex II of the Marine Equipment Directive (Module D).

The manufacturer must draw up a *Declaration of conformity to type* by himself, after the *EC type-examination procedure* and the *Production quality assurance procedure* has been completed.

This section gives a global description of the Production quality assurance procedure. Detailed description of all production phase requirements are laid down in the document: *Production quality systems, Product quality assurance and product verification* (RD_041).

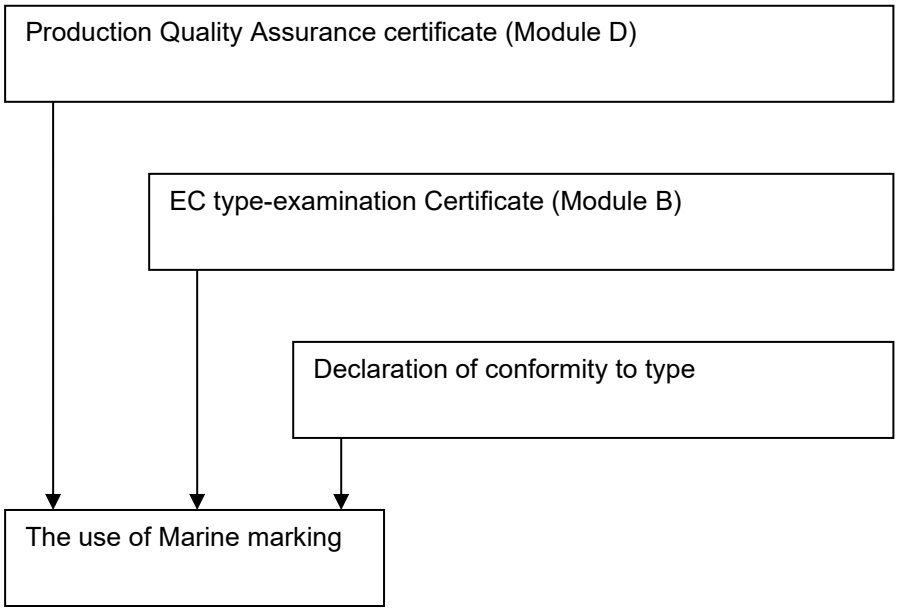

Figure 3: The Production quality assurance procedure

3.4.1 Assessment of the production quality system

The manufacturer or his European representative shall initially complete the form *Questionnaire for quality system approval* (RF_300) about the implemented quality management system with Kiwa.

The scope of the assessment depends on the product groups, the related requirements and the possible production locations. This data is asked for in the form.

The production quality system must meet the requirements of Annex II (Module D) of the Marine Equipment Directive. The manufacturer must operate an approved quality system for production, final product inspection and testing.

However, the Production quality assurance procedure includes some additional requirements regarding quality plans, product identification and traceability, subcontracting, inspection and test plans,

maintenance of quality records and internal auditing of marine equipment specific requirements. Also procedures are required for labelling, for concluding declarations of conformity to type and for liaison with Kiwa.

3.4.2 ISO 9001 certified quality systems

A Production quality system in accordance with ISO 9001 will satisfy most of the compulsory requirements. Therefore, Kiwa takes into account existing certificates, which demonstrate evidence for (parts of) the scope of the application. This means that certification/assessment reports must be available and that an accredited certification body must have issued the certificate. In this case 'accredited' means that the certification body shall comply with EN17021, assessed by an accreditation body which is member of the EA (European co-operation for Accreditation)

3.4.3 The Production quality assurance certificate

When Kiwa has successfully concluded that the quality system is in accordance with the requirements, a *Contract for production quality system approval* will be concluded with the manufacturer. With this contract the manufacturer commits himself to maintain his certified quality system and allows Kiwa the right to perform surveillance audits. After this contract is signed and returned, Kiwa will issue a *Production quality assurance certificate (Module-D Certificate)*.

Certified quality systems are subject to periodic (at least annual) surveillance audits to verify continuous compliance with the provisions of the Marine Equipment Directive.

3.4.4 Modifications to the quality system

Modification (e.g. addition of product groups or production places) are handled as an addition to an original application. The manufacturer or his European representative can request a modification by using the form *Questionnaire for quality system approval* (RF_300).

Kiwa may perform an additional assessment. The need and scope depends on the nature of modification(s) and existing experience from the previous surveillance audits performed. After the assessment has been completed successfully, the Contract for production quality system approval and the Production quality assurance certificate will be updated.

Modification to individual, approved, products are described in the sections *EC type-examination procedure* and *modifications following approval*.

3.5 Product quality assurance (Module E)

This procedure is in particular interesting if medium to high production volumes are made.

The *Product quality assurance* procedure relates to the production phase of a product. In this case the quality assurance system for final inspection and testing is assessed to verify that the manufacturer is capable of meeting the provisions of the relevant international instruments. Application for this procedure requires that the manufacturer has implemented a quality system that assures a controlled level for final product inspection and testing.

The key difference between this procedure and the Production quality assurance procedure is that here the emphasis is on final testing. This procedure does not lay down any quality system requirements on the production system.

Kiwa performs an examination of the quality system of the manufacturer. A *Product quality assurance certificate* will be issued when the quality system satisfies the requirements as laid down in Annex II of the Marine Equipment Directive (Module E).

The manufacturer must draw up a *Declaration of conformity to type* by himself, after the *EC type-examination procedure* and *Product quality assurance procedure* has been completed.

This section gives a global description of the Product quality assurance procedure. Detailed description of all production phase requirements is laid down in the document: *Production quality systems, Product quality assurance and product verification* (RD_041).

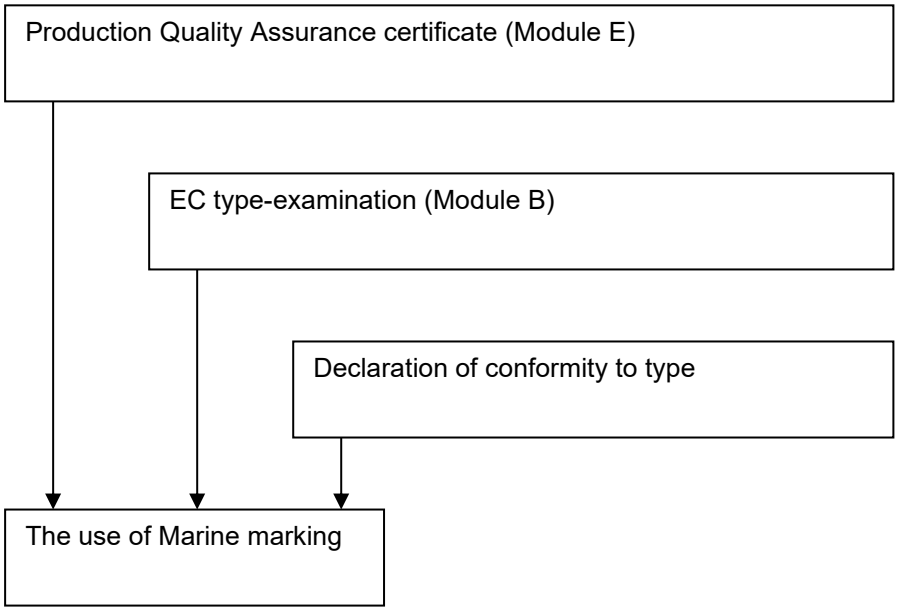

Figure 4: The Product quality assurance procedure

3.5.1 Assessment of the product quality system

The manufacturer or his European representative shall initially complete the form *Questionnaire for quality system approval* (RF_300) about the implemented product quality with Kiwa.

The scope of the assessment depends on the product groups, the related requirements and the possible production locations. This data is asked for in the form. The product quality system must meet the requirements of Annex II (Module E) of the Marine Equipment Directive. The manufacturer must operate an approved quality system for final inspection and testing which are similar to the requirements of ISO

9001. In relation with the SO 9001 requirements are the following elements not included, e.g. contract review, handling, storage, packaging, preservation and delivery.

The Product quality assurance procedure includes some additional requirements regarding quality plans, product identification and traceability, subcontracting, inspection and test plans, maintenance of quality records and internal auditing of marine equipment specific requirements. Also procedures are required for labelling, for concluding declarations of conformity to type and for liaison with Kiwa.

3.5.2 ISO 9001 certified quality systems

A Product quality system in accordance with ISO 9001 will satisfy most of the compulsory requirements. Therefore, Kiwa takes into account existing certificates, which demonstrate evidence for (parts of) the scope of the application. This means that certification/assessment reports must be available and that an accredited certification body must have issued the certificate. In this case 'accredited' means that the certification body shall comply with EN 17021, assessed by an accreditation body, which is member of the EA (European Accreditation of Certification).

3.5.3 The Product quality assurance certificate

When Kiwa has successfully concluded that the quality system is in accordance with the requirements, a *Contract for product quality system approval* will be concluded with the manufacturer. With this contract the manufacturer commits himself to maintain his certified quality system and allows Kiwa the right to perform surveillance audits. After this contract is signed and returned, Kiwa will issue a *Product quality assurance certificate*.

Certified quality systems are subject to periodic (at least annual) surveillance audits to verify continuous compliance with the provisions of the Marine Equipment Directive.

3.5.4 Modifications to the quality system

Modification (e.g. addition of product groups or production places) are handled as an addition to an original application. The manufacturer or his European representative can request a modification by using the form *Questionnaire for quality system approval* (RF_300).

Kiwa performs an additional assessment. The scope depends on the nature of modification(s) and existing experience from the previous surveillance audits performed. After the assessment has been completed successfully, the Contract for product quality system approval and the Production quality assurance certificate will be updated.

Modification to individual, approved, products are described in the sections *EC type-examination procedure* and *modifications following approval*.

3.6 Product verification (Module F)

This procedure is interesting if low production volumes or small batches are made.

The *Product verification* procedure relates to the production phase of a product. In this case there are no strict quality system requirements. At the choice of the manufacturer, Kiwa will verify the compliance with the requirements of the international instruments either by examining and testing *every product* or by means of the *application of statistical methods*.

The manufacturer must conclude a *Contract for product verification* with Kiwa when either form of this procedure is followed. The contract lays down the conditions, scope and validity regarding the Product verification procedure that is followed by the manufacturer.

The manufacturer must draw up a *Declaration of conformity to type* by himself, after the *EC type-examination procedure* and the *Product verification procedure* has been completed.

This section gives a global description of the Product verification procedure. Detailed descriptions of all production phase requirements are laid down in the document: *Production quality systems, Product quality assurance and product verification* (RD_041).

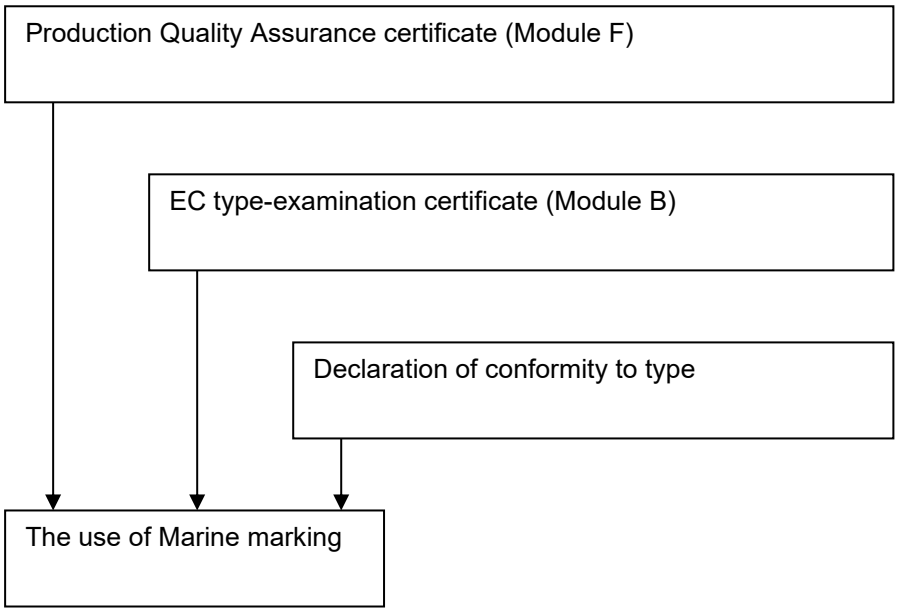

Figure 5: The Product verification procedure

3.6.1 Verification by examination and testing of every product

Applying this procedure implies that all products shall be individually examined and that the products shall be tested against appropriate requirements in order to verify their conformity to type as described in the EC type-examination certificate. Under this procedure not necessarily all test as preformed under the EC type-examination have to be repeated. Kiwa will determine - on a case-by-case basis - which tests will be applicable.

There are two possible scenario's to perform these tests:

- The test are carried out by an accredited laboratory approved by Kiwa. The test results for each individual product are forwarded to Kiwa for assessment.
- The tests are carried out by the manufacturer. In this case Kiwa will audit the testing capabilities of the manufacturer and will verify the testing and handling procedures that the manufacturer has put in place.

Upon successful completion of the examination Kiwa will issue a *Certificate of conformity* for each individual product or for each batch. The approval holder shall hold this certificate available since it can be requested for by any flag Member State's administration.

3.6.2 Statistical verification

By using this procedure, the manufacturer submits all products to a statistic verification process. The products must be available in homogeneous batches. A random sample shall be drawn from each batch. All sampled products will be subject to an individual examination and tests.

Under this procedure not necessarily all test as preformed under the EC type-examination have to be repeated. Kiwa will determine - on a case by case basis - which tests will be applicable.

There are two possible scenario's to perform these tests:

- The test are carried out by an accredited laboratory approved by Kiwa. The test results for each individual product are forwarded to Kiwa for assessment.
- The test are carried out by the manufacturer. In this case Kiwa will audit the testing capabilities of the manufacturer and will verify the testing and handling procedures the manufacturer has put in place.

The manufacturer shall apply reliable statistical methods (e.g. non-central T distribution or Binomial distribution) to determine whether any batch can be accepted or shall be rejected. In case of rejection, the manufacturer is not allowed to market any product from that batch. In the case of frequent rejections of batches, Kiwa may suspend the Contract for product verification and thereby the further application of this procedure.

Upon successful completion of the examination, Kiwa will issue a *Certificate of conformity* for each batch. The approval holder shall hold this certificate available since it can be requested for by any flag Member State's administration.

3.7 Unit verification (Module G)

This procedure is only interesting when equipment is produced individually or in extreme low volumes. This procedure can also effectively be used for prototypes of newly developed equipment for which series production is not yet envisaged.

Under the Unit verification, each individual produced product will be subject to a full EC type-examination procedure by Kiwa. Since by following this procedure each individual manufactured product is assessed to ensure the compliance with the relevant requirements of the international instruments, no production (phase) requirements are applicable.

The manufacturer must draw up a *Declaration of conformity to type* himself, after the *EC type-examination procedure* and the *Unit verification procedure* has been completed.

3.8 Compilation of Technical Documentation

For all conformity assessment modules Kiwa can assist in the compilation of the Technical Documentation in accordance MED, annex II.
The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the requirements set out in Article 4 of the MED. More details about the technical file in relation to applications to Kiwa are given in Chapter 4 of this document.

3.9 Storage of Technical Documentation

For all conformity assessment modules, Kiwa will store the technical documentation (and EU declaration of conformity) for at least 10 years after the application for the requested Kiwa service. Also if necessary and requested by the national authority, Kiwa shall provide all the information and documentation necessary to demonstrate the conformity of radio equipment.

3.10 Test laboratory

The test laboratory of Kiwa is accredited to IEC/ISO 17025. The Kiwa laboratory can assist in testing for the Modules B and G.

4 The application for “EC type-examination Certificate” (Module B)

4.1 Required documentation for Module B

The (technical) documentation to be submitted with the application must contain the information necessary to assess the product, such as:

- Signed Application form (may be filled in digitally via webportal)
- Signed Letter of Authorization
- Signed declaration that the same application has not been lodged with any other notified body
- Technical documentation according annex II of the MED

The exact required documentation is indicated in the quick reference guide RX_040.

Kiwa will guide the client by using the documentation and test results to ascertain whether the equipment satisfies all the requirements. When this is the case an EC type-examination certificate can be issued out.

4.2 Product variants

A product may be marketed in different variations, however all of these variations need to be assessed by Kiwa. OEM products and product variants can be added to an EC type-examination if they comply with the following conditions.

Product
A product is equipment that is unique in its construction.

OEM product
One may market the same product under different type designations and/or trademarks. The products are 100% identical, in construction, hardware, software and physical outlining (OEM = Original Equipment Manufacturer).

Kiwa has defined two variant categories:

Product variants category one
These are products that are almost identical; however differ in some small details. Products that fall under this category are for instance the so-called stripped versions, etc.

Product variants category two
Products that are identical at large but differ that much that they do not fall under category one, will fall under category two. Examples of these products are: a different PCB layout is used while the electronic design is the same; different options are added to the same basic product, etc

4.3 The EC type-examination certificate

For the conformity route concerning Module B, as described in section 3.3 a EC type- examination certificate will be issued. It contains:

- the name and address of the manufacturer and the certificate holder
- the name and address of the authorised representative when needed.
- the applied international instruments (standards) and data to identify the equipment
- the conclusions of the examination
- the conditions (if any) for its validity and the necessary data for identification of the assessed type.

The certificate holder can be either the manufacturer, authorized representative of the manufacturer or the importer. The standard expiration period of the certificate is 5 years.

The annexes accompanying the certificate contain information on the technical specifications on the basis of which the EC type-examination was issued and any conditions for its validity. This certificate is not transferable without the intervention of Kiwa. See also chapter 5 *'Modifications following certification'.*

Before the applicant can place marine equipment on the market, approval of the production phase must been given by a Notified Body as well. For this the *Production quality assurance procedure (Module D)*, the *Product quality assurance procedure (Module E)* or the *Product verification procedure (Module-F)* must be performed.

The manufacturer is obliged to keep the technical documentation and the EC type-examination and any follow-up certificates for at least 10 years after the last product has been placed on the market. See also chapter 6 *'The technical file'.*

Both brands follow the same conformity assessment procedures as described in Chapter 3. The certificates have the same content, but differ in visual layout for marketing purposes.

Annex D shows an example of both brands.

4.4 Follow-up to the EC type-examination certificate

Products are often modified (can be initiated by customer or notified body) after it has been certified. The manufacturer shall inform the notified body that holds the technical documentation relating to the EC type-examination certificate of all modifications to the approved type that may affect the conformity of the marine equipment with the requirements of the relevant international instruments or the conditions for validity of the certificate.

In such cases, it is often unnecessary to test all the equipment again; an additional verification and inspection will suffice. See also chapter 5 *'Modifications following approval'*.
Where necessary, Kiwa will issue a follow-up to the EC type-examination.

4.5 General requirements to issue an EC type-examination

This section describes 'The Declaration of Conformity', 'The technical file' and 'The affixing of marking' requirements that do apply to all aforementioned procedures.

4.5.1 The Declaration of Conformity

The manufacturer must draw up a *Declaration of Conformity (DoC)* for each type of equipment. This is a document in which the manufacturer or importer declares that the product in question is in compliance with the Directive 2014/90/EU (MED).

The manufacturer shall state that the fulfilment of the requirements set out in Article 4 of the MED have been demonstrated. It shall be translated into the language or languages required by the flag Member State and including at least a language commonly used in the maritime transport sector (e.g. English).

The EU declaration of conformity shall follow the model structure set out in Annex III to Decision No 768/2008/EC. It shall contain the elements specified in the relevant modules set out in Annex II to this Directive and shall be kept up to date. A model of the Declaration of Conformity is given in Annex B of this document.
More Directives can be mentioned on 1 single DoC.

The content of the DoC:

- Identification of the Marine Equipment (product, type, batch, serial)
- Name, address of manufacturer or is authorised representative
- Declaration conformity is issued under sole responsibility of manufacturer.
- Object of declaration (for traceability) is in conformity with Directive 2014/90/EU
- Description accessories and components.
- Reference to the applied international instruments.
- The applicable NB number and issued EC type certificate number.
- Signing (including name & title of signatory).
- Date and place of issue.

4.5.2 The Technical File

The manufacturer must compile a technical file. The manufacturer or his authorised representative in the EEA should keep this file for at least 10 years after the last product has been manufactured. If the manufacturer is not established in the EEA and has not appointed a representative, the file must be kept by the person who has placed the product on the market. The file is primarily intended for inspections carried out by competent national government authorities. See also chapter *The Technical File.*

4.5.3 The affixing of markings

The MED states that for Marine equipment of which the requirements laid down in the MED have been demonstrated in accordance with the relevant conformity assessment procedures shall have the wheel mark affixed to it (see also the chapter 7 *'Markings'*). If desired, the manufacturer may also affix the marking on the packaging or in the manual.

4.6 Record of complaints

The certificate holder (manufacturer, authorized representative or importer) shall keep a record of all complaints and remedial actions relative to the products covered by any certificate granted by Kiwa and to make these records available to the certification body when requested. This record shall be part of the technical file. See also chapter *'The Technical File'*.

In case such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification, appropriate action should be taken. The certificate holder should document the actions.

4.7 Termination (expiration), reduction, suspension and withdrawal of Certificates

The certificates issued by Kiwa under ISO/IEC 17065 accreditation can get a change in their active status, as published on the Kiwa website, due to passing the expiry date, changes in the prerequisites for certification, when a non-conformity with the certification requirements is substantiated or when the client requests for changes. In RQ_160 is defined for the related possibilities e.g. termination, suspension and reduction which action must be taken and how these actions have to be performed.

According article 24 of the MED the notified body is obliged to report to the notifying authority of any restriction, suspension or withdrawal of certificates.

The Kiwa procedure RQ_160 has to be followed.

4.8 Maintenance of certificates

The issued EC type-examination certificates will be kept permanently in archived digital records. Along with the certificate all used technical documentation, declarations and reports will be stored permanently.

All issued EC type-examination certificates will be added to the publication list on the Kiwa website: Search radio, wireless and electrical equipment certificates (kiwa.com)

Kiwa has the obligation to keep any issued EC type-examination to the state of art, the notified body shall inform the manufacturer accordingly. See Chapter 5 how to perform this obligation.

According article 26.4 of the MED the market surveillance authorities are empowered to withdraw products from the market and restrict placement on board of EU ships, if found that the product is not complying to the requirements and the economic operator is not taking adequate corrective actions within the timeframe given.

5 Modifications following certification

5.1 Types of modifications

One or more of the following types of modifications may be involved.

Modifications of an administrative nature:
- changes to the details of the certificate holder and or manufacturer and or authorised representative;
- change of certificate holder and or manufacturer and or authorised representative;
- alteration/addition of a type designation and/or trademark.

Modifications of a technical nature:
- addition of new product variants;
- modification of product hardware/software;
- modifications due to changing requirements;
- modifications not affecting the requirements.

5.2 Changes to the details of the certificate holder and or manufacturer and or authorised representative

In this case, the certificate holder and or manufacturer or authorised representative remains the same, but there are changes, for example, to the address, fax number or telephone number. The certificate holder and or manufacturer should inform Kiwa of the changes as quickly as possible.

Comments
Modification does not affect the conformity. Kiwa will record the new details and send the applicant a confirmation. Certificates already issued remain unchanged or can be updated on request.

5.3 Change of certificate holder and or manufacturer and or authorised representative

5.3.1 Change of the certificate holder

The EC type-examination Certificate is drawn up in the name of the certificate holder and is not transferable without the intervention of Kiwa. The name of the certificate holder can, however, be changed, in which case the new certificate holder automatically assumes all the responsibilities and obligations applicable under the issued EC type-examination in question.

Comments
The original holder of the certificate(s) must notify Kiwa in writing that the product should be transferred to the name of the new certificate-holder.[5] All the type designations and certificate numbers to which the transfer applies should be listed.

The new holder of the certificate(s) should inform Kiwa in writing that he is taking over the EC type-examination or Certificate in question, and should list all the types and certificate numbers. He should also declare, and if necessary demonstrate, that he will fulfil all the responsibilities and obligations applicable under the original type-examination. The new certificate holder draws up a Declaration of conformity for each type and sends a copy to Kiwa.

Kiwa will issue an *Follow-up to the EC type-examination*, in which the details of the new certificate holder are stated.

5 If the holder has been declared bankrupt, the receiver is the approval-holder.

5.3.2 Change of the manufacturer or authorised representative

The EC type-examination shows the name of the manufacturer and authorised representative and is not transferable without the intervention of Kiwa. The name of the certificate holder can be changed after performing a new factory inspection to cover the Modules D, E or F.

Kiwa will issue an *Follow-up to the EC type-examination*, in which the details of the new manufacturer are stated.

5.4 Alteration/addition of a type designation and/or trademark

Alteration/addition of a type designation and/or trademark means that the hardware or software remains unchanged but the type designation and/or trademark under which the product is marketed is replaced by, or extended with, a new type designation.

Comments
In this case, the old type designation and/or trademark, is replaced by a new one. It is also possible to market a product under both the old and new type designation and/or trademark. This applies to OEM products.

The certificate holder should notify Kiwa in writing of the alteration or addition of the type designation and/or trademark and declare that the new type(s) are identical to the already approved type. He should also indicate the old type designation and/or trademark and the approval/registration number and new type designation and/or trademark.

A follow-up of the EC type-examination will be issued to the certificate holder. All the relevant type designations and/or trademarks are listed in an annex of this certificate.

5.5 Addition of new products variants

Addition of new product variants means that a new product variant is added to a type. The variants must all be based on the same design and may differ only in options, version, etc.

Comments
It is possible to place several product variants under one EC type-examination, each having its own type designation and/or trademark. However, the variants must form a product family, i.e. the variations in the products must be based on the same design. It must be possible to demonstrate that the variants belong to the same type, e.g. by means of a technical examination by a designated laboratory.
Kiwa issues a follow-up of the EC type-examination in which the relevant type designations and/or trademarks are listed

5.6 Modification of product hardware/software

This means that product hardware and/or software are modified in a way that affects, or may affect, conformity with the essential requirements.

Comments
The product must be subjected to (additional) tests by the assigned laboratory. The additional test report(s) and all other altered documentation are submitted to Kiwa together with a modification application. Kiwa issues a follow-up of the EC type-examination.

5.7 Modifications due to changing requirements

As described in section 4.8 Kiwa needs to perform some maintenance on issued EC type-examinations. Kiwa will have a new system designed that allows for an automatic pick of certificates which are about to expire or need to comply on changes of standards/rules. The manufacturer will be informed on time to take adequate action.

5.8 Modifications not affecting the requirements

Technical, editorial and cosmetic modifications made to products already certified that will not affect conformity with the requirements as defined in the international instruments (standards), AND if address details of the manufacturer and certificate holder remain unchanged, AND if the product description, type designation, hardware/firmware/software versions remain unchanged, THEN it is not needed to notify (inform) Kiwa.

However, if any modification does affect one or more of the items mentioned, adequate information about the change(s) need to be provided to Kiwa. In case of any doubt Kiwa shall be informed about the case involved.

6 The Technical File

6.1 Introduction

The MED requires the manufacturer to compile a technical file. This file should contain all the technical documentation that can be used to show that the product complies with the requirements of the MED. This section provides further information on the scope, content and form of the Technical File.

6.2 Purpose of the Technical File

The technical file plays a key role in the conformity assessment of a product. The manufacturer in co-operation with the approved bodies assesses the product and keeps the (test) data in a Technical File.

The file compiled by the manufacturer is primarily intended for the national authorities responsible for inspections. The national authorities have the right to require the manufacturer, its authorized representative or importer to provide data showing that a product satisfies the requirements of the MED. If the manufacturer, its authorized representative or importer is unable or unwilling to supply this data, this provides sufficient grounds for questioning the *'presumption of conformity'* with the MED or for imposing sanctions.

In the case of products under the scope of the MED, the Technical File is one of the elements for carrying out a conformity assessment with optionally the involvement of a third party (Notified Body). In such cases, the EC type-examination issued by a Notified Body also forms part of the Technical File.

6.3 Form and content of the Technical File

The specific information that should be included in the technical file depends on the nature of the product and on the technical details needed to demonstrate that it conforms to harmonised standards. This should be indicated on a case-by-case basis, depending on the product.
It is recommended that the technical file shall be organized as follows:

- Technical documentation;
  - A general description of the product;
  - Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc;
  - Descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
  - A list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with the MED, together with a description of the solutions adopted to meet those requirements
  - Results of design calculations made, examinations carried out, etc.;
  - Test reports.
- EC type-examination;
- Declaration of Conformity;
- Packaging information;
- Records of complaints regarding the certified product(s).

Further details on the content of the technical file can be found in Annex II of the MED.

6.4 Availability of the Technical File

The technical file should always be kept available to the national authorities for inspection purposes and to Kiwa. The obligation to have at least one Technical File available on the territory of the EEA commences when the product is placed on the market of the EEA, regardless of the product's geographical origin.

The obligation to keep the Technical File available rests with the manufacturer, his authorised representative and importer established in the European Union. The file should be kept for at least ten years after the date on which the product was placed on the market.

7 Markings

All marine products within the scope of the MED are subject to labelling with the wheel mark. The exact form and conditions are described in this section.

7.1 The wheel mark

Marine equipment the compliance of which with the requirements laid down in the MED has been demonstrated in accordance with the relevant conformity assessment procedures shall have the wheel mark affixed to it. The wheel mark shall not be affixed to any other product.

The form of the wheel mark to be used shall be as shown in Figure 6.

Figure 6: Marking for marine equipment approved by Kiwa *and affixed in 2018.*

More detailed information about the Marine marking, Notified Body number and “electronic tag” are defined in the RD_104 “The affixing of marine markings”.

8 Report of granted certifications

In RQ__940 is incorporated the process of informing the relevant Authority regarding certificates and approvals granted by Certification.

Annex A, Abbreviations and paraphrases

Accredited laboratory
A laboratory operating in accordance with a quality standard -in this case ISO/IEC 17025- and which has been assessed by a recognised Accreditation Board.

Approval-holder
The person to whom an EC type-examination certificate is granted.

Authorised representative
The person who, on the explicit (written) instructions of the manufacturer, acts on his behalf or for his account with respect to the obligations laid down by Law.

Certification
A procedure whereby a third party gives written assurance that a product, process or service conforms to specified requirements (ISO/IEC Guide 2: 1991).

Compulsory certification
Certification required by a regulation or Directive before a product, process or service may be placed on the market.

Compulsory conformity assessment
Conformity assessment relating to requirements laid down in regulations or Directives which must be undertaken before a product, process or service may be placed on the market.

Conformity assessment
Systematic examination of the extent to which a product, process or service satisfies further specified requirements (ISO/IEC Guide 2: 1991).

DoC
Declaration of Conformity.
For marine equipment: A statement issued by the manufacturer in accordance with Article 16 of the MED.

EA
European co-operation for Accreditation.

EC Type-examination
A procedure whereby a Notified Body assesses the design, possibly by means of tests, of a representative specimen of the production envisaged.

EEA
The European Economic Area (EEA) comprises the fifteen member states of the EU plus Norway, Liechtenstein and Iceland.

EMC
Electromagnetic Compatibility.

EO
Economic operator

EU Ship
A ship flying the flag of a Member State and falling within the scope of the international conventions

Existing ship
A ship which is not a new ship.

Family
A type may comprise several product variants in so far as the differences between them do not affect the safety level and the other performance requirements of the product. Several family variants of the product may be marketed. These family variants are all based on the same design, but the (host-dependent) options, version, etc. differ. The product variants form, as it were, a product family only then when in all

possible configurations and/or versions at least one part for connection to the public network has certain uniqueness. Family name refers to the totality of all possible (family) variants.

FQA
Full Quality Assurance.

Full quality assurance procedure
An approval procedure in which a Notified Body assesses whether the manufacturer possesses sufficient expertise to design, test and verify products in accordance with the standard and whether he possesses a production system of a sufficiently high standard to guarantee that the products satisfy the (statutory) requirements. (EN-ISO9001 quality systems.)

Importer
Any person who places a product from a third country (defined as a country outside the EEA), on the market of the EEA.

International conventions
- the 1996 International Convention on Load Lines (LL66), and;
- the 1972 Convention on the International Regulations for Preventing Collisions at Sea (Colreg), and;
- the 1973 International Convention for Prevention of Polution from Ships (marpol), and;
- the 1974 International Convention for the Safety of Life at Sea (Solas);
  together with their Protocols and the amendments thereto in force on 1 January 1999.

International instruments
International instruments means the international conventions, together with the resolutions and circulars of the IMO giving effect to those conventions in their up-to-date version, and the testing standards;

ISO/IEC 17025
General requirements for the competence of testing and calibration laboratories is the main ISO standard used by testing and calibration laboratories.

ISO 9000
A group of international standards, comprising both quality management and quality assurance.

LVD
Low Voltage Directive (Directive 2014/35/EU).

Making available on the market
Making available on the market means any supply of marine equipment on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

Manufacturer
Any natural or legal person who manufactures marine equipment or has marine equipment designed or manufactured, and markets that equipment under its name or trademark

Marine equipment
Equipment falling within the scope of the Marine Equipment Directive in accordance with Article 3.

MLA
Multilateral Recognition Agreement.

Notified Body
A Notified Body is a third party authorised to carry out the tasks relating to approvals described in a European Directive. In general, a Notified Body can be regarded as a competent approvals body in a field where approval (certification) of a product is compulsory by law. A Notified Body is designated by the State. A member state of the EEA (European Economic Area) can only designate bodies falling within its sphere of competence.

Bodies designated by a member state should satisfy criteria relating to proficiency, independence, impartiality, etc. In this connection, European standard EN17065 is particularly important. The body is

then notified to the European Commission and the other member states of the EEA and thereby acquires the status of 'Notified Body'.

OEM products
A certificate holder may market the same product under different type designations and/or trademarks. One Statement is issued for the product in which all the relevant type designations and/or trademarks are listed. (OEM = Original Equipment Manufacturer.)

Placed on board
Equipment installed or placed on board a EU ship.

Placing on the market
The first making available of marine equipment on the Union market.

Product
An item of marine equipment.

Production quality assurance procedure
An approval procedure in which a Notified Body assesses whether the manufacturer's production process is of a sufficiently high standard to guarantee that the products satisfy the (statutory) requirements. (ISO 9001 quality systems.)

Putting into service
The first use by the end user within the EC, of a product covered by a Directive.

PQA
Production Quality Assurance.

QMS
Quality Management System.

Radiocommunications equipment
Equipment required by Chapter IV of the 1974 SOLAS Convention, in the version in force on 1 January 1999, and survival craft two-way VHF radiotelephony apparatus required by Regulation III/6.2.1 of the same Convention.

RvA
Raad voor Accreditatie (The Dutch Council for Accreditation).

MED
Marine Equipment Directive

MED Package
A Compliance Management service of Kiwa.

Safety certificates
Certificates issued by or on behalf of Member States in accordance with international conventions.

Standard
A standard is a technical specification drawn up by a recognised standards organisation (ISO, CEN, CENELEC or ETSI) for repeated or continuous application, but with which compliance is not necessarily compulsory.

Certificate holder
The person to whom a EC type-examination has been granted.

TD
Technical Documentation

Technical specification
A technical specification is the specification contained in a document which lays down the characteristics required of a product such as quality levels, performance, safety, dimensions, including the requirements

applicable to the product as regards terminology, symbols, tests and test methods, packaging, marking and labelling.

Kiwa
Certification services of Kiwa – Third party certification body accredited by The Dutch Council for Accreditation (Raad voor Accreditatie: RvA).

Testing standards
The testing standards for marine equipment set by:
- the International Maritime Organization (IMO);
- the International Organization for Standardization (ISO);
- the International Electro technical Commission (IEC);
- the European Committee for Standardization (CEN);
- the European Committee for Electro technical Standardization (CENELEC);
- the International Telecommunication Union (ITU);
- the European Telecommunication Standards Institute (ETSI);
- the Commission, in accordance with Article 8 and 27(6) of the MED;
- the regulatory authorities recognised in the mutual recognition agreement to which the Union is a party.

Trademark
Trademark refers to the generic (brand) name under which a product is marketed.

Type designation
Type designation refers to the unique name under which a product is marketed.

Annex B, Declaration of conformity

Declaration of conformity

We (Name and address manufacturer)

hereby declare entirely on our own responsibility that the product:
(Name, type, batch or serial number)

with the following accessories and components:
(only if applicable)

for which the following standard(s) or normative document(s) have been applied:
(Titles and publication dates of the applicable international instruments)

Conform to EC Type-examination certificate: xxxxxxxxxxxxx
Issued by Notified Body:
Kiwa Nederland B.V. (NB# 0063)
Wilmersdorf 50, 7327 AC, Apeldoorn, The Netherlands

Is in compliance with the provisions of European Directive 2014/90/EU and Implementing Regulation (EU) 2018/773.

(Place and date)

(Name, title and signature)

Annex C, Forms and documents

General
Several forms and documents are available to assist you in applying for product approvals or quality system assessments. The list below covers the most important documents.

For EC type-examination and product approval:

RD_040 Conformity Assessment procedures for Marine Communication, Navigation Fire Protection and Lifesaving Equipment, (this document).

RF_041 Declaration of conformity (MED)

RQ_940 Report of granted approvals/certifications

For quality system assessment:

RD_041 Production quality systems and Product quality systems and Product verification

RF_300 Questionnaire for quality system approval

Kiwa provide you with original copies of these forms (RF) and documents (RD), but you can also use photocopies or printouts obtained from our web-site. Downloads - Kiwa W&E

Annex D, Format of EC type-examination Certificate

D.1 EC type-examination with Kiwa B.V. brand (Module D)

CERTIFICATE

Certificate of
Production Quality System
Pxxx (issue x)

MODULE D

Telefication, operating as Notified Body under the Directive 2014/90/EU, hereby declares that the produced products of the company:

[Name Client]

[Applicable Manufacturing Site]:

complies with the certification criteria as laid down in RD_040 and RD_041 implementing the Production Quality System requirements of the **Marine Equipment Directive 2014/90/EU.**

The certification covers the Production Quality System as well as the specified product description as described in annex 1, which is provided with this certificate.

Date of issue:
Date of first issue:
Expiration date:

Ron Scheepers
Managing Director

0063

This Certificate has two Annexes.

Kiwa Nederland B.V.
Kiwa Wireless & CMC
Wilmersdorf 50
Postbus 137
7300 AC Apeldoorn
The Netherlands

https://www.kiwa.com

Annex 1 Certificate of Production Quality Sytem

Pxxx (issue x)

page 1 of 1

Remarks and observations

The following conditions are applicable:

Authorized representative:

Annex 2 Certificate of Production Quality Sytem

Pxxx (issue x)

page 1 of 1

Module D Scope:

+ including implementing regulation (EU) 2021/1158
# including implementing regulation (EU) 2022/1157

D.2 EC type-examination with Kiwa brand (Module B)

CERTIFICATE

EC type-examination certificate (Module B)

<certificate number>

Product Category: <Registration No>

USCG Approval No: <FRN USCG>

Issued	<date>	**Date of expiration of validity**	<expiry date>
Page	<Page> of <NumPages> **This certificate has THREE Annexes.**	**Last date of placement**	

In compliance with the procedure specified in the **Marine Equipment Scheme** RD_040, Kiwa Nederland B.V. declares as designated Notified Body 0063 for the Marine Equipment Directive, that the stated product complies with Directive 2014/90/EU and Implementing Regulation <Regulation>, based on the applicable international instruments and test standards as listed in Annex 2 of this certificate.

Product description:	<xxx>
Trademark:	<xxx>
Type designation:	<xxx>
Hardware / software:	<xxx> / <xxx>
Variants:	See Annex 3

Manufacturer: <xxx>
Address: <xxx>
City: <xxx>
Country: <xxx>

This certificate is granted to:

Name: <certificate holder>:
Address:
City:
Country:

PRODUCTS
RvA C 002

Ron Scheepers
Managing Director

Kiwa Nederland B.V.
Wilmersdoc 50
Postbus 137
7300 AC Apeldoorn
The Netherlands

https://www.kiwa.com/nl/en/markets/radio-wireless-and-electrical-equipment/

Chamber of commerce
08090048

Annex 1 to EC type-examination cerificate <certificate number>

page 2 of 6

General Conditions

- This EC type-examination certificate is limited to the Marine Equipment Directive.
- Each product to which this certificate relates shall be provided with Marine markings. The Marine marking consists of symbol in the form of a wheel followed by the identification number of the responsible Notified Body for Module D, E, F or G, and by the last two digits of the number of the year in which the mark is affixed.
- The holder of this certificate has drawn up a Declaration of Conformity to type with Directive 2014/90/EU and Implementing Regulations, declaring that the product(s) described in this EC type-examination certificate, satisfy the requirements that apply to them.
- The validity of this EC type-examination certificate is limited to products, which are equal to the one(s) assessed for this EC type-examination.
- Each product shall be identified by means of type, batch and/or serial numbers and the name of the manufacturer and/or importer.
- If the equipment is to be modified, Kiwa shall be notified immediately. Depending on the modifications, Kiwa may have additional examinations carried out in consultation with the applicant.
- Enforcement of a new amending directive or new Implementing Regulation may void the validity of this EC type-examination certificate regarding (re)placement of the product onboard ships.

Remarks and observations

The following conditions are applicable:

Annex 2 to EC type-examination certificate <certificate number>

page 3 of 6

Documentation lodged for this EC type-examination certificate

Test Reports:

Product Documentation:

International Instruments and test standards

The product is compliant with:

<Applied Standards>

Annex 2 to EC type-examination certificate <certificate number>
page 4 of 6

Technical features and characteristics

The product includes the following features and characteristics:

Annex 3 to EC type-examination certificate <certificate number>

page 5 of 6

The product as described in this certificate includes the following type designations:

Annex E, Additional information

For more information contact:

Kiwa Nederland B.V.

Phone: +31 88 998 3600
Fax: +31 316583189
Email: certification@Kiwa.com

Mailing Address:
Wilmersdorf 50
7327 AC Apeldoorn
The Netherlands

website: http://www.kiwa.com