

Marine Equipment Questions and Answers

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1 Definitions

1.1 'Marine equipment/products'

'Marine equipment' means equipment/products falling within the scope of Marine Equipment Directive 2014/90/ EU.

The Implementing Regulations to the Directive indicate:

- the design, construction and performance requirements and testing standards of marine equipment,
- alternative modules for conformity assessment, as well as
- the dates from which the testing standards are to apply or their validity ends.

The 3rd Implementing Regulation (EU) 2019/1397 is applicable since 3rd of October 2019 and will apply until replaced by the 4th Implementing Regulation and any following. The latest Implementing Regulation as well as the MED Directive are published on the DNV GL's MED Website.

Example:

1. Life-saving appliances					
Column 2: IMO MSC/Circular 980 shall apply except when superseded by the specific instruments referred to in Column 2.					
Number and item designation	Regulations of SOLAS 74, as amended, and the relevant resolutions and circulars of the IMO, as applicable	Testing standards	Modules for conformity assessment	First placing on the market	Last placing on board
1	2	3	4	5	6
MED/1.1 — Lifebuoys	Type approval requirements — SOLAS 74 Reg. III/4, — SOLAS 74 Reg. X/3.	— IMO Res. MSC.81(70), as amended.	B+D B+E B+F		
	Carriage and performance requirements — SOLAS 74 Reg. III/7, — SOLAS 74 Reg. III/34, — IMO Res.MSC.36(63)-(1994 HSC Code) 8, — IMO Res.MSC.48(66)-(LSA Code) I, — IMO Res.MSC.48(66)-(LSA Code) II, — IMO Res.MSC.97(73)-(2000 HSC Code) 8.				

'product' means an item of marine equipment (Lifebuoys-MED/1.1)

1.2 'Manufacturer'

'Manufacturer' means 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. The manufacturer is bringing this product under his own tradename into the market. The manufacturer is issuing the Declaration of Conformity for the related equipment. The Obligations for manufacturers are described in Article 12 of MED 2014/90/EU.

1.3 'Place of Production/Production Site'

On this place the equipment/product will be produced, and wheel marked. The listening of several places of production (name and address) for this equipment/product is possible. The places of production are part of the assessment of the quality system for production (audit).

1.4 'Authorized Representative'

'Authorized representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks.

2 Authorized representative

2.1 Who need to have an Authorized Representative?

A manufacturer who is not located in the EU shall, by a written mandate, appoint an Authorised Representative located in the EU and shall indicate the name and the address of the Authorised Representative which can be contacted.

Please see also Article 13 of MED 2014/90/EU Authorized Representative. The Authorized Representative can apply for EC certification for the manufacturer.

3 EC certificates

3.1 What is needed to bring products acc. to MED into the EU market?

To be able to bring the MED equipment/products into the EU market a valid EC Certification of the following Module combinations is necessary: B+D or B+E or B+F or G

- Module B: EC Type examination of the product design
- Module D: Assessment of the quality system for production to ensure that the products will be produced conform to type as described in Module B
- Module E: Assessment of the quality system for the product to ensure that the products will be produced conform to type as described in Module B
- Module F: Verification of single products or statistical verification of homogeneous lots to ensure the conformity with the type as described in the Module B
- Module G: Assessment of the design and testing of a single product, to ensure the conformity with the requirements

The Implementing Regulation shows the allowable module combinations for each MED item.

3.2 How long are my EC certificates valid?

The Module B certificate (Type EC Assessment of product), the Module D certificate (Quality Assessment of production) and the Module E certificate (Quality Assessment of product) are valid until their expiry date, unless otherwise indicated by later Implementing Regulations issued after the EC certificate.

There is no time limitation for the validity of a Module F certificate (Assessment of Product series) and a Module G certificate (Single Unit verification).

If the product is changed or new Implementing Regulations to MED introduces changes to requirements/testing standards, a Re-Assessment by a notified body is necessary. After such Re-Assessment with positive result, revised EC certificates will be issued.

It is the responsibility of the manufacturer to monitor the introduction/status of Implementing Regulations and identify any changes in the requirements that applies to their products.

3.3 Where EC certificates will be published?

The data of EC certificates, which were issued by DNV GL are published on the DNV GL Approval Finder accessible at DNV GL's Website: <https://approvalfinder.dnvgl.com/>. Furthermore, relevant data about EC certifications will be reported to EMSA MED database on monthly basis.

4 Mark of Conformity-Wheel mark

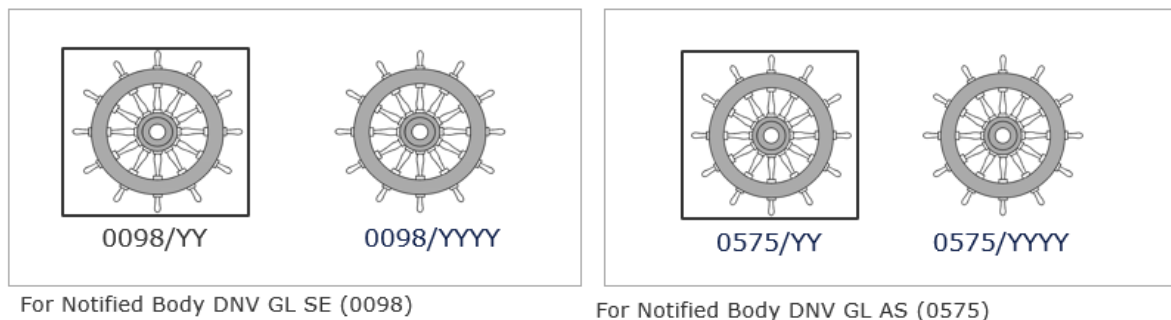
4.1 When the Wheel mark shall be affixed on the product?

The product shall be wheel marked at the end of the production phase. The wheel mark shall be followed by the number of the notified body which was issuing Module D/E or F/G and the year of production.

4.2 How shall a Wheel mark look like?

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

Illustration



Furthermore, manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification. In addition, they shall indicate their name, registered trade name or registered trademark and the address at which they can be contacted on the product.

5 EU Declaration of Conformity (DoC)

5.1 What is a DoC?

EU Declaration of Conformity is a statement by the manufacturer that fulfilment of the requirements relating to the product has been demonstrated.

The product is produced in a period where the manufacturer holds valid EC certificates. By drawing up and signing the EU Declaration of Conformity, the manufacturer assumes responsibility for the compliance of the product.

5.2 How shall a DoC look like?

Please see an example of a DOC, which is based on the template provided in the MarED Document no. 17-693 IN ADCO MED DoC Template from 2017-11-15). The DoC may be formatted according to the manufacturers design and layout guideline.

EC Declaration of conformity

We hereby declare that the following specified equipment complies with the Marine Equipment Directive 2014/90/EU and Implementing Regulation (EU) xxxx/xxxx ¹

Equipment description: _____

Type: _____

Serial number/unique reference ²: _____

Manufacturer: _____

Manufacturer Address: _____

This equipment has been tested to verify compliance with the following Regulations and Testing Standards: _____

As per:

EC Type-Examination Certificate No./Rev.³ (for module B): _____

Issued By (Notified Body name/number): _____

Quality System Certificate No./Rev. ³ (for module D & E): _____

Issued By (Notified Body name/number): _____

Certificate of Conformity No./issue date ³ (for module F & G): _____

Issued By (Notified Body name/number): _____

The technical documentation for this equipment is retained at the following address: _____

Place: (place) Date: (yyyy-mm-dd)

Appointed by the manufacturer as the responsible person for signing this Declaration.

(name/title)

Address _____

¹ Include reference to latest Implementing Regulation valid at the time of production. This may be different from the Implementing regulation stated on the EC certificate.

² Serial number, lot, batch, etc.

³ Data from the valid EC certificate(s)/ modules applied should be listed.

5.3 Who needs to have the DoC?

Acc. to the MED2014/90/EU Article 16 (4) :“When marine equipment is placed on board an EU ship, a copy of the EU declaration of conformity covering the equipment concerned shall be provided to the ship, and shall be kept on board until the said equipment is removed from the ship....

It shall be translated by the manufacturer into the language or languages required by the flag Member State, including at least a language commonly used in the maritime transport sector. “

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.