Specific certification regulation Marine Directive (MED)

Scientific and Technical Centre of the Belgian Textile Industry

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1 Introduction

The European Directive on Marine Equipment or MED 2014/90 makes it mandatory to affix the wheel mark on products that are used as marine equipment. By affixing the wheel mark, the manufacturer* attests that the product is in conformity with the applicable legal safety and health requirements and that it is marketed in conformity with the legislation. The technical requirements with which the products have to comply are defined in the corresponding harmonized European standards or technical specifications.

* *Manufacturer: natural person or legal entity that manufactures a product or that has it designed and manufactured and sells it under his name or trademark.*

The Directive subdivides the equipment in different categories to which different conformity assessments apply. These categories are:

1. Life-saving appliances
2. Marine pollution prevention
3. Fire protection equipment
4. Navigation equipment
5. Radio-communication equipment
6. Equipment required under COLREG 72
7. Bulk carrier safety equipment
8. Equipment under SOLAS Chapter II-1
9. Equipment for which the set of standards for MED certification is not complete

In category 3: Fire protection equipment, CENTEXBEL is accredited for the certification of the following equipment:

Fire protection equipment: **MED/3.3** Firefighter equipment: protective clothing
Fire protection equipment: **MED/3.5** Firefighter equipment: protective gloves
Fire protection equipment: **MED/3.18** Surface materials and floor covering with a low flame spread: a) decorative veneers; b) paint systems; c) floor coverings; d) pipe insulation covers; e) adhesives used in the construction of 'A', 'B' & 'C' class divisions; f) combustible ducts membrane.
Fire protection equipment: **MED/3.19** Draperies, curtains and other suspended textile materials and films
Fire protection equipment: **MED/3.20** Upholstered furniture a) complete piece of furniture (including cover material, filling material and non-flammable rack) b) cover material for any filling material c) cover material for flame-retardant filling material (tested in specific combination as intended for further application) d) flame-retardant filling material
Fire protection equipment: **MED/3.21** Bedding components

The manufacturer* shall affix the wheel mark after a notified body has performed a type examination based on the former's technical file and after a verification has been performed by a notified body. The manufacturer* may choose the verification system to be followed:

- production-quality assurance (module D)
- product-quality assurance (module E)
- product verification (module F)

The manufacturer* shall affix the wheel mark, followed by the notified body's identification number that will perform the periodical conformity assessments and the equipment's production date. This date can be applied 20XX or XX.

CENTEXBEL is a notified body number 0493 and is authorized to perform the type examination and periodical conformity assessments according to the three verification systems mentioned above.

2 Definitions

See General Certification Regulation

3 Certification procedure

3.1 EC-Type Examination Module B

After concertation with the applicant, the *EC-type examination* is performed. As a guide, the technical file is used, that is based on the MED regulations, and more in particular on annex II and on the applicable harmonized standards or other technical specifications. During this examination, models are also submitted to the tests as foreseen in the corresponding harmonized standard or technical specifications. These tests are performed in the CENTEXBEL laboratories or by a recognized subcontractor in conformity with the requirements of ISO 17025.

The *product certifier* drafts a report with remarks and hands it over to the applicant. The latter is requested to provide the necessary clarifications and/or perform the necessary corrections or submit the missing documents as soon as possible. CENTEXBEL provides a maximum period of 6 months hereto. If CENTEXBEL has not received the missing documents, clarifications or corrections within 6 months, the file will be automatically put on hold and the reopening of the file after 6 months will give rise to new certification costs (ISO 17065 §7.4). Only when a positive response is given to all remarks, the product certifier shall submit a written proposal to grant the certificate of type examination to the certification manager of CENTEXBEL. If it is impossible to prove conformity, the product certifier will submit a proposal to refuse the certificate of type examination to the certification manager.

In order to be permitted to affix the wheel mark, the applicant shall dispose of a module B certificate in combination with a module D, E or F certificate.

3.2 Production-quality assurance (module D)

After concertation with the applicant, the production-quality assurance or FPC audit is performed. The FPC checklist is used as a guide to this audit. The focus of the audit is on the production of the product (or product group).

The FPC auditor drafts an audit report and hands it over to the applicant and the product certifier.

If no immediate corrective actions are required, the product certifier shall submit a proposal of decision for the intended product (or product group) to the Certification manager of CENTEXBEL.

If non-conformities have been observed during the audit, a timespan, depending on the nature of the non-conformity, shall be communicated in which the non-conformity shall be solved.

3.3 Product-quality assurance (module E)

After concertation with the applicant, the product-quality assurance or FPC audit is performed. The FPC checklist is used as a guide to this audit. The focus of the audit is on the production of the product (or product group).

The FPC auditor drafts an audit report and hands it over to the applicant and the product certifier.

If no immediate corrective actions are required, the product certifier shall submit a proposal of decision for the intended product (or product group) to the Certification manager of CENTEXBEL.

If non-conformities have been observed during the audit, a timespan, depending on the nature of the non-conformity, shall be communicated in which the non-conformity shall be solved.

3.4 Product verification (module F)

Every year, CENTEXBEL shall contact the certificate holder to carry out examinations and tests to check the conformity of the products (or product groups) with the appropriate requirements. The product certifier carries out the examination by taking samples at the manufacturer* that are representative for the production and by having the necessary tests carried out on them.

Thereupon, the product certifier drafts an expertise report, including the findings of the examination. The report establishes whether the product (group) is still in conformity with the requirements of the legislation and corresponds with the model that was offered at the type examination as well as any corrective actions and their deadlines. The proposed actions shall be in proportion with the impact of the shortcomings on the safety and health of the user.

The product certifier submits his/her expertise report with proposal for certification decision to the certification manager.

4 Obligations of the manufacturer*

The manufacturer* shall respect the applicable provisions of the European Marine Equipment Directive 2014/90/EC. If the manufacturer* appeals to one or more harmonized standards or technical specifications, that give a presumption of conformity with the essential requirements of the equipment, he shall also respect the provisions thereof.

1. By affixing the wheel mark, manufacturers shall take on responsibility for guaranteeing that the marine equipment to which the mark is affixed has been designed and manufactured in accordance with the technical specifications and standards implemented in accordance with Article 35(2), and shall assume the obligations laid down in paragraphs 2 to 9 of this Article.
2. Manufacturers shall draw up the required technical documentation and have the applicable conformity assessment procedures carried out.
3. Where the compliance of marine equipment with the applicable requirements has been demonstrated by the conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity in accordance with Article 16 and affix the wheel mark in accordance with Articles 9 and 10.
4. Manufacturers shall keep the technical documentation and the EU declaration of conformity referred to in Article 16 for at least 10 years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned.
5. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in marine equipment design or characteristics and changes in the requirements in the international instruments as referred to in Article 4, on the basis of which conformity of marine equipment is declared, shall be taken into account. When necessary in accordance with Annex II, manufacturers shall have a new conformity assessment carried out.
6. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product or both, as appropriate.
7. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate. The address must indicate a single point at which the manufacturer can be contacted.
8. Manufacturers shall ensure that the product is accompanied by instructions and all necessary information for safe installation on board and safe use of the product, including limitations of use, if any, that can be easily understood by the users, together with any other documentation required by the international instruments or testing standards.
9. Manufacturers who consider or have reason to believe that a product to which they have affixed the wheel mark is not in conformity with the applicable design, construction and performance requirements and with the testing standards implemented in accordance with Article 35(2) and (3), shall immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or to recall it, if appropriate. In addition, where the product presents a risk, manufacturers shall immediately inform the competent national

authorities of the Member States, giving details, in particular, of the non-compliance and of any corrective measures taken.

10. Manufacturers shall, further to a reasoned request from a competent authority, promptly provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by or is acceptable to that authority, grant that authority access to their premises for market surveillance purposes in accordance with Article 19 of Regulation (EC) No 765/2008 and provide samples or access to samples in accordance with Article 25(4) of this Directive. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.
11. Manufacturers shall fulfil the obligations mentioned in article 16 regarding the drafting of a EU declaration of conformity and supply of a copy of the EU declaration of conformity to the notified body (notified bodies).