The Marine Equipment Directive and the EC-US Mutual Recognition Agreement on marine equipment

Guidance for manufacturers
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1. The Marine Equipment Directive (MED)

1.1 Introduction


The MED covers those types of equipment required to be fitted under the four International Conventions developed by the International Maritime Organization (IMO), namely:

LOADLINE 1966
SOLAS 74 – Life-saving Appliances/Navigation Equipment/Radio Equipment
MARPOL 1973 – Marine Pollution
COLREGS 1972 – Prevention of Collisions

Amendments are made to the MED by the Commission to reflect amendments made to the Conventions and associated Codes by IMO Resolutions and Circulars.

These changes are published as an Amending Directive, at approximately 12-18 month intervals.

Care should be taken in selecting the appropriate amendment and reference to your local Lloyd’s Register office is advised before undertaking any substantive product design or testing.

1.2 Equipment covered by the MED

The main purpose of Council Directives is to ensure that latest standards are applied; they update both Annexes A.1 and A.2. Normally only dates of entry into force are amended in the main Directive 96/98/EC.

Annexes A.1 and A.2 list different equipment categories in the Sections below where x represents a particular equipment item:

Annex A.1 is published in tabular form listing all the types of equipment to which the main Directive’s requirements now apply.

Annex A.2 contains types of equipment for which internationally agreed testing standards do not yet exist in international instruments. The equipment types are tabulated in similar format to Annex A.1 but with the major difference that at time of issue of the amending Commission Directive, the EC MED does not apply to any of the equipment listed. When agreement on testing standards has been reached for one or more equipment items, a subsequent amendment will transfer them across into Annex A.1.

If a product is listed in Annex A.2 then MED is not currently applicable. No direct action needs to be taken but manufacturers should have a watching brief as their product will be included in A.1 at some stage.

The 6 columns of both Annexes detail the following information:

Col 1: Item No (for particular equipment types).
Col 2: Item designation (generic equipment type).
Col 3: Regulation(s) of the applicable Convention specifying that ‘type approval’ is required.
Col 4: Regulations as above specifying the relevant resolutions and circulars of IMO which specify that ships must carry or be fitted with the equipment type of Col 2.

Col 6: Modules for conformity assessment (See below).

1.3 Conformity with the MED

Conformity is initially demonstrated when one or more prototypes of a design have been independently witnessed as having been satisfactorily tested thus confirming that the performance parameters applicable to equipment of that type have been achieved. An EC Certificate of Type Examination will be issued by a Notified Body such as Lloyds Register Verification. This is a Module B Certificate and forms one part of the Conformity Route.

The standards to which the prototype was constructed then form the ‘benchmark’ against which all subsequent production of the design will be measured to ensure that they also achieve the same or better performance parameters.

Annex B of the MED gives details of the various Modules of which Module B above is one.

Column 6 of Annex A.1 lists one or more Modules that in combination can be used for conformity assessment of production (the Conformity Route). In the majority of cases a Module B Certificate is necessary and this must be used in combination with one of the other Production Modules - D, E, or F.

It should be noted that the Notified Body issuing the EC Type Examination Certificate (Module B) need not necessarily also be the Notified Body issuing the production certification – the Certificate of Conformity of the production Modules D, E, F or G.

Figure 1: the manufacturer’s route to conformity with the MED.
1.4 **Module D – (Production Quality Assurance) and Module E – (Product Quality Assurance)**

Applicable primarily to those manufacturers having large throughput, production Modules D and E both require a manufacturer to operate an approved Quality System (QS) which has the ability to control production of one or more product types (products of one or more Item Designations).

1.4.1 **Module D (Production Quality Assurance)**

Module D requires an operational QS which has detailed procedures documented and when correctly used and maintained will ensure that all production results in equipment items which meet the ‘benchmark’ standard of the prototype to which a Module B certificate was awarded. In progress checks and testing are expected to be used.

1.4.2 **Module E (Product Quality Assurance)**

Module E also requires an operational QS whose documented procedures are used to confirm after manufacture that all production has resulted in equipment items which meet the ‘benchmark’ standard of the prototype to which a Module B certificate was awarded. This is normally achieved through a post-production inspection/testing regime. Use of either of these two Modules allows the manufacturer to issue final documentation without the presence of the Notified Body; however, the MED does require the Notified Body to monitor the manufacturer’s operation of the Quality Management System at regular and/or variable intervals.

1.4.3 **Module D and E Assessments**

The Notified Body is required to carry out an initial assessment of a manufacturer’s QS during which qualified auditors familiar with the type of equipment being produced will review the documented system and observe its implementation. They will prepare a report indicating any omission of procedures necessary to implement the additional requirements of the MED.

A follow-up visit will be made when the manufacturer has updated his QS and can demonstrate that all concerned are aware and ready for the changes that implementation will bring. If satisfactory, the Notified Body will issue a Certificate of Conformity for the system detailing the product designations of Annex A.1 that it may control, this is also the manufacturer’s authorisation from the Notified Body to affix the ‘mark of conformity’ (the ‘Wheelmark’) to his products.

The manufacturer can then issue his own Declaration of Conformity (See below).

1.5 **Module F – Product verification**

Module F (Product verification) is applicable to manufacturers whose production is mainly in smaller batches or lots of the same or differing item designations. Each product type of the same item designation must have been awarded a Module B certificate.

Under Module F the Notified Body has to be advised in advance of intended production and will liaise to agree a schedule for carrying out the verification. Normally experienced surveyors who may or may not also be auditors will attend to examine the batches and will select samples to be more closely examined and tested to the requirements of the applicable testing standards. They will review the manufacturer’s records of production to ensure conformity with the benchmark prototype(s) and if all is found to be in order will issue the manufacturer with a Certificate of Conformity listing batch and serial numbers. This document is the manufacturer’s authorisation from the Notified Body to affix the ‘mark’ (the ‘Wheelmark’) to his products.
The manufacturer can then issue his Declaration of Conformity to their customer detailing amongst other descriptive and prescribed data, the Conformity Route used (the numbers of both the Module B Certificate and that of the Certificate of Conformity).

1.6 **Module G – Unit verification**

For very few types of equipment, usually of a one-off nature, Module G (Unit verification) alone is applicable. In this case no Module B is applicable since Module G requires that all Prototype Tests are conducted on every individual product, followed by whatever Production Tests are required by the applicable standards. The Notified Body will conduct surveys during construction and witness tests.

Upon completion of manufacture and testing the Notified Body’s Surveyor will issue the manufacturer with a Module G Certificate of Conformity relating to an individual item or small batch of equipment items. The manufacturer can then apply the ‘Wheelmark’ and issue a final documentation including his Declaration of Conformity to the customer detailing the Conformity Route used.

1.7 **Affixing the Mark of Conformity**

The format of the Mark of Conformity or ‘Wheelmark’ is specified in Annex D of the MED. It is the sign that the product is declared by its manufacturer to conform to type and therefore be in compliance with SOLAS (or other Convention) performance requirements.

The Mark has to be followed by the identification number of the Notified Body which has performed the conformity-assessment procedure of the production-control phase, and by the last two digits of the year in which the mark is affixed. The normal format is as shown on the front cover with ‘0038’ being the Lloyd’s Register Verification number and the ‘yy’ representing the last two digits of the year of manufacture.

By way of explanation, the Notified Body issuing the EC Type Examination Certificate (Module B) need not necessarily also be the Notified Body issuing the production certification – the Certificate of Conformity of the production Modules D, E or F.

1.8 **Declaration of Conformity**

A manufacturer’s Declaration of Conformity is a descriptive document which as a minimum for clarity should describe the product, state the MED’s Annex A.1 Item No and item designation, and should also include:

(a) Manufacturers Name & Address.

(b) Description of Product and state its manufacturer’s Type No. or Code

(c) List Standards with which it is declared to comply

(d) Notified Body authorising the affixing of the Mark – Name & Address.

(e) Conformity Route used

(f) EC Type Examination Certificate No. (unless Module G used)

(g) Certificate of Conformity No. (for QS when Modules D or E)

(h) Serial numbers and batch/lot identification (if applicable)

(i) Identification of signatory and their authority to sign D o C’s
There is no mandatory format although the EC do recommend EN 45014 and manufacturers are at liberty to customise their Declarations. A template is available from MarED for manufacturers to use, an example of the Lloyd’s Register format is shown below.

![Lloyd's Register Declaration of Conformity](image)

**Figure 2: The Lloyd’s Register Declaration of Conformity format.**
Figure 3: How to achieve MED certification.
2. The EC-US Mutual Recognition Agreement (MRA) on Marine Equipment

2.1 Introduction

Negotiations on an important mutual recognition agreement between the United States (US) and the European Community (EC) were concluded in June 2003 and the agreement was signed on February 27, 2004. The EC completed their internal ratification process in April 2004 and published the EC-US MRA on Council Decision 2004/425/EC of 21st April 2004, the required exchange of letters being finished in May 2004. The official implementation date for this Agreement was July 1st, 2004.

The agreement aims to simplify matters for the manufacturers that wish to have both US Coast Guard (USCG) type approval and the European Certificates of Conformity (see definition). The US-EC Mutual Recognition Agreement (MRA) on Marine Equipment is a result of a 5-year cooperative effort that recognizes the importance of facilitating US-EC trade in marine equipment and promoting bilateral cooperation on the international marine equipment regulations.

The EC-US MRA will allow a manufacturer to reach multiple markets on the basis of compliance with one set of regulatory requirements instead of multiple ones, as would the case without the MRA. This can lead directly to a reduction of costs for the manufacturer in terms of testing and certification.

The initial MRA product scope includes 43 products in 3 main categories: life saving appliances (e.g. visual distress signals, marine evacuation systems); fire protection equipment (e.g. fire door installations) and navigational equipment (e.g. compass, GPS equipment, and echo sounding equipment). This agreement also contemplates expanding the product scope in the future for items where it can be agreed that the requirements are equivalent. The complete listing of eligible products are contained in Annex II of the MRA (please see overleaf).

While there will be no further certification requirements, the Parties may maintain their respective requirements with regard to the marking according to Article 5 of the EC-US MRA. Therefore, equipment listed in the Agreement that is certified and marked as complying with the MED when placed in the US market will have to be additionally marked with a USCG approval number as required by the US legislation and regulations without the need to carry out further conformity assessment.

2.2 Marking of products under the EC-US MRA

There are three scenarios for marking of MED approved products covered by Annex II of the EC-US MRA according to U.S. Coast Guard instructions, which are briefly described as follows.

1. Where Lloyd’s Register Verification issue both the EC Type Examination (Module B) Certificate and the QA Certificate of Conformity Module D/E/F or. This scenario also applies when issuing the Module G Certificate of Conformity.

2. Where Lloyd’s Register Verification issue the EC Type Examination (Module B) Certificate only.

3. Where Lloyd’s Register Verification issue the QA Certificate of Conformity (Module D, E, F) only.

2.2.1 Where Lloyd’s Register Verification issue both the Module B and Module D, E or F

(a) The EC Type Examination (Module B) Certificate will be reissued with the EC-US MRA marking required on the front page and also a paragraph will be added which states:
“This product has been assigned a U.S. Coast Guard Module B number <USCG Approval Category/EC0038/MED Module B Cert. No.> to note type approval to Module B only as it pertains to obtaining US Coast Guard approval as allowed by the “Agreement between the European Community and the United States of America on Mutual Recognition of Certificates of Conformity for Marine Equipment” signed February 27th, 2004.”

Reference should be made to the U.S. Coast Guard approval categories for the correct product given in the table in Appendix 1. The unique identifier used by Lloyd’s Register Verification is the MED Module B Certificate number, but other Notified Bodies may assign a different number (e.g. a sequential number, etc.).

(b) The Certificate of Conformity (Module D or E) will be reissued with the EC-US MRA marking required and the following paragraph:

“The manufacturer is allowed to affix the US Coast Guard approval number <USCG Approval Category/EC0038/MED Module B Cert. No.> as allowed by the “Agreement between the European Community and the United States of America on Mutual Recognition of Certificates of Conformity for Marine Equipment” signed 27 February 2004.”

When a Certificate of Conformity (Module F) is to be issued for units or lots for which a USCG Module B number has already been allocated, then the Certificate of Conformity shall also include the above paragraph.

When a Certificate of Conformity (Module G) is to be issued for products within Annex II of the EC-US MRA, the above paragraph in italics will also be added to the Certificate and the USCG Approval number will be assigned directly.

As you may note, when a single Notified Body issues both the Module B and the QA Conformity Module (D, E or F), the USCG Module B number on the MED Module B Certificate and the USCG Approval number on the MED QA Module Certificate will be the same.

Only when a Certificate of Conformity complying with the above has been issued is the manufacturer allowed to mark the equipment with the USCG Approval number provided. Please note that no Declaration of Conformity is required to meet the U.S. Coast Guard requirements, but it continues to be mandatory for the EC market as required by the MED.

2.2.2 Where Lloyd’s Register Verification issue the EC Type Examination (Module B) Certificate only

The Module B certificates will be reissued with the EC-US MRA required marking on the front page and paragraph as described in section 1(a) above.

The manufacturer should then approach the Notified Body who provides the QA module (D, E or F). Such notified Body shall use the U.S. Coast Guard Module B number allocated by Lloyd’s Register Verification to provide the manufacturer with the U.S. Coast Guard approval number by noting it on the Certificate of Conformity, thereby authorizing the manufacturer to mark the product accordingly.
2.2.3 Where Lloyd’s Register Verification issue the QA Certificate of Conformity (Module D, E, F) only

If Lloyd’s Register Verification has not issued the EC Type Examination (Module B) Certificate, the manufacturer is to supply the unique identifier provided by the relevant Notified Body for the applicable product(s).

The Certificate of Conformity (Module D, E or F) will be issued by Lloyd’s Register Verification with the EC-US MRA marking required and the following paragraph,

“The manufacturer is allowed to affix the US Coast Guard approval number <USCG Approval Category/ECXXXX/Unique Identifier/EC0038> as allowed by the “Agreement between the European Community and the United States of America on Mutual Recognition of Certificates of Conformity for Marine Equipment” signed 27 February 2004.”

Where “ECXXXX” is the Notified Body number of the body issuing the Module B Certificate, “Unique identifier” is the number assigned by such Notified Body and “EC0038” is the Notified Body identification of Lloyd’s Register Verification.

Once a Certificate of Conformity complying with the above has been issued, the manufacturer is then allowed to mark the equipment with the USCG Approval number provided.

Please note that no Declaration of Conformity is required to meet the U.S. Coast Guard requirements, but it continues to be mandatory for the EC market as required by the MED.

**Note:** it is the manufacturer’s responsibility to ensure that a mechanism is in place to keep abreast of any amendments to the MED, EC-US MRA and Annexes.
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Figure 4: How to comply with the EC-US MRA on Marine Equipment.
## 3. Appendices

### Appendix 1 – USCG approval categories for products listed in Annex II of the EC-US MRA

#### Fire protection

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<td>Primary deck coverings</td>
<td>164.106</td>
<td>A.1/3.1</td>
</tr>
<tr>
<td>“A” and “B” Class division fire integrity</td>
<td>164.105** (deck assembly)</td>
<td>A.1/3.11</td>
</tr>
<tr>
<td></td>
<td>164.107** (structural insulation)</td>
<td>A.1/3.11</td>
</tr>
<tr>
<td></td>
<td>165.108** (bulkhead panels)</td>
<td>A.1/3.11</td>
</tr>
<tr>
<td>Structural ceiling</td>
<td>164.110** (structural ceiling)</td>
<td>A.1/3.11</td>
</tr>
<tr>
<td>Non-combustible material</td>
<td>164.109</td>
<td>A.1/3.13</td>
</tr>
<tr>
<td>Draperies, curtains &amp; other suspended textiles</td>
<td>164.111</td>
<td>A.1/3.19</td>
</tr>
<tr>
<td>Surface materials and floor coverings with low flame-spread characteristics</td>
<td>164.112*** (interior finish)</td>
<td>A.1/3.18</td>
</tr>
<tr>
<td></td>
<td>164.117 (floor coverings)</td>
<td>A.1/3.18</td>
</tr>
<tr>
<td>Fire doors</td>
<td>164.136*</td>
<td>A.1/3.16*</td>
</tr>
<tr>
<td>Penetrations through ‘A’ class divisions by electric cables, pipes, trunks, ducts etc.</td>
<td>164.138</td>
<td>A.1/3.26</td>
</tr>
<tr>
<td>Penetrations through ‘B’ class divisions by electric cables, pipes, trunks, ducts etc.</td>
<td>None</td>
<td>A.1/3.27</td>
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<tr>
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<tr>
<td>Fire door control systems</td>
<td>164.146</td>
<td>A.1/3.17</td>
</tr>
</tbody>
</table>

* Limited to fire doors without windows and doors with total window area of 645 cm², or less, in each door leaf. Approval limited to maximum door size tested. Doors must be used with a fire tested frame design.

** Does not include “A” or “B” class windows.

*** Limited to exposed surfaces of ceilings, walls, and floors. Does not apply to pipes, pipe coverings, or cables.
## Lifesaving appliances

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<thead>
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</tr>
<tr>
<td>Rocket parachute flare (pyrotechnics)</td>
<td>160.136*</td>
<td>A.1/1.8</td>
</tr>
<tr>
<td>Hand flares (pyrotechnics)</td>
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<tr>
<td>Rigid liferaft</td>
<td>160.118*</td>
<td>A.1/1.13</td>
</tr>
<tr>
<td>Automatically self-righting rigid liferaft</td>
<td>160.118*</td>
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</tr>
<tr>
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<td>FLOAT free (hydrostatic release units)</td>
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<td>A.1/1.16</td>
</tr>
<tr>
<td>Release Mechanism for lifeboats, rescue boats, liferafts launched by a fall or falls</td>
<td>160.133*</td>
<td>A.1/1.26</td>
</tr>
<tr>
<td>Marine Evacuation system</td>
<td>160.175</td>
<td>A.1/1.27</td>
</tr>
</tbody>
</table>

* Expiration date not to exceed 48 months after month of manufacture.
* The emergency pack is not covered by the MRA.
* Limited to davit-launched liferaft automatic release hook.
# Navigation equipment

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<td>Magnetic compass</td>
<td>165.101</td>
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</tr>
<tr>
<td>Transmitting Magnetic Heading Device, TMHD (formerly Electromagnetic compass)</td>
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<td>Rate of turn indicator</td>
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<td>Electronic Plotting Aid³</td>
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<td>Integrated bridge system</td>
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<td>Equipment</td>
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<td>Track Control</td>
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<td>Radar Reflector</td>
<td>165.160</td>
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</table>

1. Expiration date not to exceed 48 months after month of manufacture.
2. The emergency pack is not covered by the MRA.
4. Radio transmitter is required to be authorized by U.S. Federal Communications Commission (FCC).
Appendix 2 – Example of marking of products under the EC-US MRA
Appendix 3 – Terms and definitions

Administration: means the Government of the State whose flag the ship is entitled to fly.

Authorised representative: in the meaning of the New Approach directives, it is any natural or legal person established inside the European Community and appointed by the manufacturer to act on his behalf in carrying out certain tasks required in the Directive. The delegation of tasks from the manufacturer to the authorised representative must be explicit and should take place in writing.

Certificate of Conformity: the document or documents issued by a Conformity Assessment Body of a party certifying that the product fulfils the relevant legislative, regulatory and the administrative requirements of that Party. In the United States (US), this is the Certificate of Type Approval issued by the United States Coast Guard. In the European Community (EC), they are certificates, approvals and declarations foreseen by Council Directive 96/98/EC, as amended.

Conformity Assessment Body: means a legal entity, whether a Regulatory Authority or another body, public or private, that has the authority to issue Certificates of Conformity under a Party’s domestic laws and regulations. Specifically:

1) The notified Bodies designated by the EC Member States under Directive 96/98/EC;
2) The U.S. Coast Guard.

Declaration of Conformity: a descriptive document issued by the manufacturer under the MED system and provided to the customer.

Equivalence of technical regulations: means that the technical regulations of the Parties relate to a specific product are sufficiently comparable to ensure that the objectives of each Parties’ respective regulations are fulfilled. Equivalence to technical regulations does not mean that the respective technical regulations are identical.

Manufacturer: in the meaning of the New Approach directives, is any natural or legal person who is responsible for designing and manufacturing a product with a view to placing it on the European Community market under his own name. The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes, or labels readymade products with a view to their being placed on the EC market under his own name. The manufacturer has sole and ultimate responsibility for the conformity of the product.

Marine Equipment Directive: Council Directive 96/98/EC of 20 December 1996 of marine equipment, as amended. This is commonly referred to as the MED.

MARED: the co-ordinating group of the Notified Bodies assigned by the Member States to carry out the conformity evaluation procedures referred to in the Marine Equipment Directive.
Mark of Conformity: marking affixed to products as an indication of compliance with the Marine Equipment Directive (MED). The mark shall be followed by the identification number of the Notified Body which has performed the conformity-assessment procedure (e.g. 0038 for Lloyd’s Register Verification) and by the last two digits of the number of the year in which the mark is affixed (yy).


Notified Body: a body authorised by the competent National Administration of a Member State to carry out work in accordance with the MED.

Notified Body Number: is a unique four digit identifier issued to each Notified Body. The number is included as part of the MED “Mark of Conformity”.

International Instrument: means the relevant international conventions, resolutions and circulars of the International Maritime Organization (IMO), and the related test standards, (e.g. FTP Code, LSA Code).

Regulatory Authority: means a government agency or entity that has the authorisation to issue regulations regarding issues related to safety at sea and prevention of marine pollution, that exercises a legal right to control the use, installation, or sale of marine equipment within a Party’s jurisdiction, and that may take enforcement action to ensure that products marked within its jurisdiction comply with the applicable legal requirements. The parties respective Regulatory Authorities are identified in Annex III of the MRA.

Technical regulations: comprise the mandatory product requirements, testing and performance standards and conformity evaluation procedures laid down in the legislative, regulatory and administrative provisions of the Parties related to the marine equipment, as well as any applicable guidelines for their application.

The Parties: in this document, the United States of America and the European Community Member States.

Wheel mark: the term commonly used to describe the marking affixed to products as an indication of compliance with the Marine Equipment Directive (MED). More properly called the ‘Mark of Conformity’