MED 2014/90/EU

Marine Equipment Directive
Cooperation of NB with Market Surveillance Authorities

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EMSA

MED Presentation - Contents

- The MED of 2014 and the MED Portal
- The MSA Agreements – requesting info to Manufacturers
- MSA tailored DoC according to NB outputs
- ICSMS and Cooperation with MSA
- Questions

Legal Context – Implementation
The MED of 2014 and the MED Portal

How the access to the market worked in the 1980's?...

And then...the New Approach...and much learning on the way...

EU Treaty – Policy

- Maritime Transport Safety (Art.70(c))
- Environmental Protection (Art.174)
- Internal Market (Art.5, 83(b), 85(1), 85(2), 95, 133)

Marine Equipment Directive – Law

- Article 34 – Commission Obligation to sep up MarED Group

Implementation – EMSA Remit

- Regulation (EC) 1406/2002 – Technical/scientific advice to COM

Outcome – MED Portal – Documentary Data Base

- Technical Secretariat for MarED Group – QMS's TS MarED

The MED Portal is for ALL MED Skateholders

MSA Agreements – Requesting info to Manufacturers (1)

Information to be provided to the Marine Equipment Directive's Market Surveillance Authority of

EU MS / EFTA MS

Before *(Date)*

Refer to your product: ***(Insert Name, Model, brief description as per MED item designation)***

Please set up an electronic file and send back it to the following e-mail address: ***MSA e-mail address***

The expected electronic file shall contain, as sorted in the order shown below, the following information:

MSA Agreements – Requesting info to Manufacturers (2)

1. Authorized Representative in the EU: Name, post address and e-mail. (where applicable).

2. Declaration of conformity

3. Your current production reference EC Type Examination Certificate (Module B)

Test report related to the Module B certificate

4. Latest follow up of the production Certificate (Module choose D/E/F)

Latest test reports carried out for your product by you as manufacturer in your factory:

- ***Before manufacture (for Module D only)***
- ***During manufacture (for Module D only)***
- After manufacture (for all Modules)

Latest test reports carried out for your product by you as manufacturer and witness by your Notified Body in your factory:

- ***Before manufacture (for Module D only)***
- ***During manufacture (for Module D only)***
- After manufacture (for all Modules)

MSA Agreements – Requesting info to Manufacturers (3)

5. List of trademarks, models, variants, commercial names etc corresponding to the product undergoing the current market surveillance investigation.

6. List of factories producing the same product.

* * *

According to the index above, the overall number of documents expected to be contained within the file requested by this MSA, for your product manufactured as per (please, choose one of the following options)

MED Module D requirements is: 14 documents.

MED Module E requirements is: 10 documents.

MED Module F requirements is: 10 documents

MSA – Tailored DoC according to NB outputs

1. NB are the closest MED stakeholder to manufacturers
2. Manufacturers must be instructed
3. Adopted by ADCO MED on 20 October 2020

ADCO MED EU DECLARATION OF CONFORMITY

TEMPLATE

(to be used for marine equipment within the scope of DIRECTIVE 2014/90/EU)

ADCO MED Model EU DECLARATION OF CONFORMITY rev 20 10 2020 (1).pdf

MSA – Tailored DoC according to NB outputs

MED EU DECLARATION OF CONFORMITY TEMPLATE (to be used for marine equipment within the scope of DIRECTIVE 2014/90/EU)

1. No … (unique identification of the product): [Give type, batch or serial number(s) as appropriate]
2. Name and address of the manufacturer (and his authorised representative, if applicable):
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate): [Give MED entry number and description (e.g. MED/1.11 Linethrowing appliances), current version of implementing act and model and brand names, etc., Product description as given for EC type examination certificate]
5. The object of the declaration described above is in conformity with Directive 2014/90/EU

MSA – Tailored DoC according to NB outputs

6. References to the relevant performance requirements and test standards - specifying also year of issue, version, dates - in relation to which conformity is declared: *[Typically references to IMO documents and IEC, ISO, EN standards given in the relevant item in the implementing act and the Notified Body's EC type examination certificate]*

7. The notified body/bodies *[give name(s) and number(s)]* performed a *[as appropriate indicate the used modules: B+D, B+E, B+F, G]* conformity assessment procedure and issued the certificate(s): …*[Indicate the certificate numbers, validity of Modules D and E].*

8. Additional Information - Application and / or limitations (if any), as specified in EC Type Examination Certificate (Module B or G): *[Any limitations on the acceptance or use of the product or specific requirements stipulated in the relevant section of SOLAS, MARPOL, LSA, etc. or any other condition of validity - such as life rafts height of stowage, …..].*

Signature: Signed for and on behalf of: ……

(place and date of issue): (name, function) (signature)

* * *

ICSMS and Cooperation with MSA

ADCO Group = {MSA(EU MS)$_i$, MSA (EFTA MS)$_j$}

ADCO Group meets twice a year (by June and November)

ICSMS = daily / permanent contact –

Restricted to EU MSA

And USCG where the MED item is into EU-USA MRA

Cooperation:

MED Art 33 – among MSA

MED Art 24 – NB and NA (then MSA)

MED Art 24 – NB and NA

Article 24

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 a conformity certificate;

(b) any circumstances affecting the scope of, and the conditions for, notification;

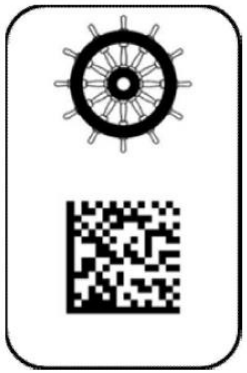
(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(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.

MED Approval – Public outcome – MED Database (art. 35.4)

195.000 entries registered!



EMSA MED Intranet Public PT NB (RISE) TS

HOME PRODUCTS EVENTS DOCUMENTS DISCUSSIONS WORKING SHEETS RECOMMENDATIONS MEMBERS MY ORGANIZATION

MED ITEM NUMBER	COMMERCIAL PRODUCT NAME	COMMERCIAL MODEL NAME	MANUFACTURER NAME	MANUFACTURER COUNTRY	NOTIFIED BODY NUMBER	NOTIFIED BODY NAME	DETAIL
MED/4.23	Magnetic compass Class B for lifeboats and rescue boats		RIVIERA SOCIETA' A RESPONSABILITA' LIMITATA GENOVA	Italy	0474	RINA Services S.p.A.	
MED/4.23	MAGNETIC COMPASS CLASS B FOR LIFEBOATS AND RESCUE BOAT		PLASTIMO SAS	France	2690	Bureau Veritas Marine & Offshore	
MED/4.23	MAGNETIC COMPASS CLASS B FOR LIFEBOATS AND RESCUE BOAT		PLASTIMO SAS	France	2690	Bureau Veritas Marine & Offshore	
MED/4.23	COMPASS FOR LIFEBOATS AND RESCUE BOATS		PLASTIMO SAS	France	2690	Bureau Veritas Marine & Offshore	
MED/4.23	Magnetic compass Class B for lifeboats and rescue boats		RIVIERA SOCIETA' A RESPONSABILITA' LIMITATA GENOVA	Italy	0474	RINA Services S.p.A.	
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ICSMS and Cooperation with MSA

MSA share much of the following information:

- **Member States:** market surveillance programmes
- **Market Surveillance actions:** - manufacturers,
  - distributors,
- **Ship inspections:** flag activities,
- **Cooperation:** RAPEX, ICSMS and ADCOs

  Rules for products presenting a serious risk and restrictive measures

Thank you for your attention!

Lisbon 10 Nov 2021

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facebook.com/emsa.lisbon

EMSA