



FOCA AltMoC

Alternative Means of Compliance

Anticoagulation Medication not requiring INR Monitoring

This document is an 'Alternative Means of Compliance' issued by FOCA



Source: imago GmbH, 13127 Berlin

Scope	Thromboembolic Disorders, removal of limitations for Class 2 Medical Certificates
Applies to	Aircrew (Class 2 pilots)
Valid from	01 November 2018
Purpose	Compulsory / Information

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This document is an

Alternative Means of Compliance (AltMoC) issued by FOCA

according to

Regulation (EU) No 1178/2011 (Air Crew), ARA.GEN.120, or
Regulation (EU) No 965/2012 (Air Operations), ARO.GEN.120

Preliminary Information

What is an AltMoC issued by FOCA?

The EASA homepage on the internet states (as of end 2016):

‘Since AMCs are non-binding, regulated persons may choose alternative means to comply with the rule. In this case, however, they lose the presumption of compliance provided by the EASA AMC, and need to demonstrate to competent authorities that they do comply with the law.

The implementing rules for Aircrew licensing, Air Operations, Aerodromes and Air Traffic Controller licensing describe the process to be used by regulated persons and competent authorities when they intend to use an AltMoC to comply with the rules.

Implementing Rules establish that the implementation of AltMoC by organisations is subject to prior approval by the competent authority and indicate what needs to be done in order to obtain the approval.

Implementing Rules also establish the obligations of competent authorities when giving the prior approval to an organisation and when they adopt themselves an AltMoC that can be used by the regulated organisations under their oversight.

One of the obligations stipulated in the Implementing Rules is to notify EASA of such AltMoCs. Competent authorities are requested to use the EASA prepared AltMoC Notification Form for notifying AltMoCs proposed by organisations or used by themselves.

For more information from EASA on AMC and AltMoC, please consult the [FAQ](#).’

To these statements FOCA would like to add the following additional information:

- AltMoCs may not only be issued as alternative to an already existing AMC. FOCA may as well publish AltMoCs that cover issues where no AMC is available. Therefore, the term *alternative* may be slightly misleading in some cases.
- AltMoCs may be seen as an administrative ordinance in traditional Swiss legal doctrine. However, conditions, issuing power and legal effects are pure products of Union legislation. Legal practitioners, attorneys and courts in Switzerland, therefore, should not attempt to categorise AltMoCs under traditional national principles of administrative law. They should always bear in mind that AltMoC are genuine legal instruments of the EU aviation safety regulation.

What are the effects of an AltMoC issued by FOCA?

AltMoCs issued by FOCA have basically the same legal status and effect as AMCs. Except that the author of AltMoCs is not EASA but FOCA. AltMoCs are not evaluated by EASA in advance but are reviewed within a short time after their publication by FOCA. Therefore, once released by FOCA, AltMoCs become immediately applicable to all parties under Swiss jurisdiction. In other words, they immediately may be used as an alternative to existing AMCs or they must be used if no such AMC is available. In either case they provide presumption of conformity with the essential requirements and the implementing rules.

However, AltMoCs do not have cross-border effect: an operator under foreign jurisdiction has no legal claim to his competent authority to allow use of an AltMoC issued by FOCA. And FOCA will not automatically accept in its jurisdiction the use of an AltMoC issued by foreign competent authorities.

Different matters are AltMoCs developed and requested by an ATO, operator or regulated person and which are not issued but only approved by FOCA. These have effect for the applicant only. Third parties must submit a complete application for their own including full proof that their AltMoC fulfils the legal requirements.

AltMoC may motivate EASA to initialise own rule making aiming an additional IR or additional AMC. The start of such rule making procedure does *senso stricto* not have any effect on the AltMoC until the time where a revised IR or a new AMC legally replaces the AltMoC. However, such rule making activities might increase the likelihood that competent authorities accept the underlying foreign AltMoC.

1 Implementing Rule – MED.B.010 Cardiovascular

Ch. 1 ISS 1 / REV 0 / 01.11.2018

MED.B.010 Cardiovascular

(b) Cardiovascular System – General

(3) Applicants for a Class 1 medical certificate with an established history or diagnosis of any of the following conditions shall be referred to the licensing authority:

(viii) arterial or venous thrombosis

(ix) pulmonary embolism

(x) cardiovascular condition requiring systemic anticoagulant therapy

(4) Applicants for a Class 2 medical certificate with an established diagnosis of one of the conditions specified in (2) and (3) above shall be assessed by a cardiologist before a fit assessment can be considered in consultation with the licensing authority.

1.1 Acceptable Means of Compliance

Ch. 1.1 ISS 1 / REV 0 / 01.11.2018

AMC2 MED.B.010 Cardiovascular system

(g) Thromboembolic disorders

Arterial or venous thrombosis or pulmonary embolism are disqualifying whilst anticoagulation is being used as treatment. After 6 months of stable anticoagulation as prophylaxis, a fit assessment with multi-pilot limitation may be considered after review by the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. Pulmonary embolus should require full evaluation.

1.2 Regulatory wording of the AltMoC

Ch. 1.2 ISS 1 / REV 0 / 01.11.2018

Applicants following thromboembolic disorders on prophylactic anticoagulation medication not requiring INR monitoring (e.g. NOACS, DOACS) may be considered for unrestricted Class 2 Medical certification in consultation with the licensing authority after a stabilisation period of 3 month.

1.3 Summary of the AltMoC Assessment

Ch. 1.3 ISS 1 / REV 0 / 01.11.2018

Assessed as meeting the Implementing Rule MED.B.010.

The role of N/DOACs in the prevention, treatment and prophylaxis against recurrence has been widely accepted in therapeutic medicine. Their efficacy, compliance and safety profile has been established in many trials. A meeting convened by EASA in Berlin in 2013 found the use of N/DOACs compatible with flight safety.

EASA has published a draft AMC (August 2016) proposing that the safety pilot and single pilot limitations may be omitted from Class 2 certification in applicants treated prophylactically with this medication.

The use of risk assessment tools available to the treating physician enables the determination of risk associated with this therapy. The low risk of both recurrence and hemorrhage is compatible with unrestricted Class 2 Medical certification.