This Notification Completion Instruction Sheet will provide you with any additional instructions and requirements necessary to complete the AltMoC Notification Form. It is strongly recommended to use the English language in completing the form. Please complete the form in a **clearly legible** way.

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| **# - Field Name** | **Completion Instructions** |
| **1.1 Name of the CA** | Name of the CA notifying the AltMoC. |
| **1.2 AltMoC focal point** | Indicate the title, the first name, the name and the job title of the person in the CA to whom further communication on this AltMoC should be addressed. |
| **1.3 Contact details of the AltMoC focal point** | Include the email address and the telephone number of the AltMoC focal point in the CA. |
| **2.1 Subject** | Briefly indicate the issue that the AltMoC intends to address. |
| **2.2 Regulatory reference** | Indicate the Regulation that the AltMoC refers to (ex: Regulation (EU) 1178/2011). |
| **2.3 Implementing rule (IR) paragraph(s)** | Indicate the paragraph(s) of the IR(s) to which the AltMoC refers to (ex: FCL.055). |
| **2.4 Agency acceptable means of compliance (AMC) available** | Indicate whether there is already an Agency AMC on the same issue. If so, include the reference(s) (ex: AMC 2 FCL.055). |
| **2.5 AltMoC proposer** | Indicate whether the AltMoC was proposed by an organisation **or** is used by a CA by ticking in a box.  • If proposed by an organisation, provide the organisation’s name and the date (dd/mm/yyyy) the proposed AltMoC was approved by the CA.  • If used by a CA, provide the date (dd/mm/yyyy) when the AltMoC was made available to all the organisations and the persons under its oversight. |
| **2.6 AltMoC based on an AltMoC from another CA** | Please indicate whether this AltMoC is based on an AltMoC from another CA and, if yes, indicate which CA. |
| **2.7 Summary of the AltMoC** | Summarise the AltMoC, describing how it proposes to achieve compliance with the rule. |
| **2.8 Summary of the AltMoC assessment** | Summarise the assessment you performed, and why you concluded that compliance with the rule is achieved by this AltMoC. |
| **2.9 Attachments to the AltMoC notification form** | Tick in the relevant boxes to make sure you submit all the required documentation when notifying the Agency of an AltMoC.  AltMoC proposed by an organisation:  • Full organisation’s description of an AltMoC should include at least reasoning of the AltMoC;  • CA’s evaluation of the AltMoC;  • CA’s signed statement that the AltMoC was assessed by the CA and it establishes compliance with the IR(s). ***Note:*** *CA’s assessment also includes an evaluation of an AltMoC’s risk assessment where relevant.*  AltMoC used by the CA itself:  • Full description of an AltMoC should include at least the reasoning of the AltMoC;  • CA’s assessment demonstrating that the IR(s) are met;  • Regulatory wording of the CA’s used AltMoC. |
| **2.10 List of the attachments in addition to the above required if relevant** | Indicate the number of documents you attach and include a brief description of each of them (ex: organisation’s internal procedures, studies or safety assessments) if in addition to the above requested. |
| **3.1 Other Member States have been informed about the organisation proposed AltMoC** | Indicate whether other MS have been informed about the organisation proposed AltMoC, which has been approved by the CA. And if ‘yes’ then please specify means of informing other MS. |
| **4. Date and signature** | The form should be dated (dd/mm/yyyy) and signed by the AltMoC focal point indicated under 1.2. By signing the form the CA’s focal point confirms that all of the information provided in the AltMoC Notification form is correct and complete. |