

develop on products identified in this rulemaking action.

### Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

**2023–01–12 Safran Helicopter Engines, S.A. (Type Certificate Previously Held by Turbomeca, S.A.):** Amendment 39–22306; Docket No. FAA–2023–0021; Project Identifier MCAI–2022–01618–E.

#### (a) Effective Date

This airworthiness directive (AD) is effective February 6, 2023.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to all Safran Helicopter Engines, S.A. (Type Certificate previously held by Turbomeca, S.A.) Arriel 1C, Arriel 1C1, and Arriel 1C2 model turboshaft engines.

#### (d) Subject

Joint Aircraft System Component (JASC) Code 7200, Engine (Turbine/Turboprop).

#### (e) Unsafe Condition

This AD was prompted by reports of false engine fire warnings. The FAA is issuing this AD to prevent false engine fire warnings. The unsafe condition, if not addressed, could lead

to commanded in-flight engine shut-down, possibly resulting in damage to the helicopter and reduced control of the helicopter.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Perform all required actions within the compliance times specified in, and in accordance with European Union Aviation Safety Agency (EASA) AD 2022–0256, dated December 19, 2022 (EASA AD 2022–0256).

#### (h) Exceptions to EASA AD 2022–0256

(1) Where EASA AD 2022–0256 requires compliance from its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the “Remarks” section of EASA AD 2022–0256.

(3) Although the service information referenced in EASA AD 2022–0256 specifies to discard any removed fire detectors, this AD requires removing those parts from service.

#### (i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0256 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

#### (j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD and email to: [ANE-AD-AMOC@faa.gov](mailto:ANE-AD-AMOC@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

#### (k) Additional Information

For more information about this AD, contact Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; email: [kevin.m.clark@faa.gov](mailto:kevin.m.clark@faa.gov).

#### (l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0256, dated December 19, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0256, contact EASA, Konrad-Adenauer-Ufer 3, 50668

Cologne, Germany; phone: +49 221 8999 000; email: [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu). You may find this material on the EASA website at [ad.easa.europa.eu](http://ad.easa.europa.eu).

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

Issued on January 13, 2023.

**Gaetano A. Sciortino,**

*Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2023–01113 Filed 1–18–23; 11:15 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA–2023–0020; Project Identifier MCAI–2022–01566–E; Amendment 39–22305; AD 2023–01–11]

**RIN 2120–AA64**

### Airworthiness Directives; Safran Helicopter Engines, S.A. (Type Certificate Previously Held by Turbomeca, S.A.) Turboshaft Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** The FAA is adopting a new airworthiness directive (AD) for all Safran Helicopter Engines, S.A. (Safran) Makila 1A and Makila 1A1 model turboshaft engines. This AD was prompted by reports of false engine fire warnings. This AD requires replacing the affected fire detectors, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also prohibits the installation of affected fire detectors. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective February 6, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 6, 2023.

The FAA must receive comments on this AD by March 6, 2023.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*AD Docket:* You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-0020; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

*Material Incorporated by Reference:*

- For EASA material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu); website: [easa.europa.eu](https://easa.europa.eu). You may find this material on the EASA website at [ad.easa.europa.eu](https://ad.easa.europa.eu).

- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-0020.

**FOR FURTHER INFORMATION CONTACT:**

Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238-7088; email: [kevin.m.clark@faa.gov](mailto:kevin.m.clark@faa.gov).

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA-2023-0020; Project Identifier MCAI-2022-01566-E” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may

amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to [regulations.gov](https://www.regulations.gov), including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

**Confidential Business Information**

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

**Background**

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022-0244, dated December 8, 2022 (EASA AD 2022-0244), (also referred to as the MCAI), to correct an unsafe condition for all Safran Makila 1A and Makila 1A1 model turboshaft engines. The MCAI states that there were reports of false engine fire warnings. The subsequent investigation results identified a manufacturing non-compliance on the fire detectors, which caused a shift of the detection threshold towards temperature values that are lower than specified, potentially leading to a false engine fire warning. When two engines on a helicopter are fitted with an affected part, an engine fire warning could occur on both engines during the same flight. This condition, if not addressed, could lead to commanded in-flight engine shut-down, possibly resulting in damage to the helicopter and reduced control of the helicopter.

The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-0020.

**Related Service Information Under 1 CFR Part 51**

The FAA reviewed EASA AD 2022-0244, which specifies procedures for replacing affected fire detectors. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in

**ADDRESSES.**

**FAA’s Determination**

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI described above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

**AD Requirements**

This AD requires accomplishing the actions specified in EASA AD 2022-0244, except for any differences identified as exceptions in the regulatory text of this AD. This AD also prohibits the installation of affected fire detectors.

**Explanation of Required Compliance Information**

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2022-0244 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2022-0244 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022-0244 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance

Time(s)” in EASA AD 2022–0244. Service information required by EASA AD 2022–0244 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–0020 after this AD is published.

**Justification for Immediate Adoption and Determination of the Effective Date**

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity

for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because fire detectors that do not conform to the type design could lead to false engine fire warnings. Safran was informed of three occurrences of illumination of the engine fire alarm without confirmed fire (untimely illumination) on airframes equipped with affected fire detectors. False engine fire warnings are an unsafe condition requiring urgent corrective action because, if a helicopter is equipped with two engines with an affected fire detector installed, an engine fire warning could occur on both engines during the same flight. This unsafe condition, if not addressed, could lead to commanded in-flight engine shut-down, possibly resulting in damage to the helicopter and reduced control of the helicopter. Replacement of the fire detectors must be accomplished within 30 flight hours or 60 days from the effective date of this AD, whichever

occurs first. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

**Regulatory Flexibility Act (RFA)**

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

**Costs of Compliance**

The FAA estimates that this AD affects 1 engine installed on a helicopter of U.S. registry. The FAA estimates the following costs to comply with this AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace fire detectors .....	1 work-hour × \$85 per hour = \$85 .....	\$1,800	\$1,885	\$1,885

**Authority for This Rulemaking**

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs describes in more detail the scope of the Agency’s authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

**Regulatory Findings**

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

**The Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

**PART 39—AIRWORTHINESS DIRECTIVES**

- 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

**2023–01–11 Safran Helicopter Engines, S.A. (Type Certificate Previously Held by Turbomeca, S.A.):** Amendment 39–22305; Docket No. FAA–2023–0020; Project Identifier MCAI–2022–01566–E.

**(a) Effective Date**

This airworthiness directive (AD) is effective February 6, 2023.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to all Safran Helicopter Engines, S.A. (Type Certificate previously held by Turbomeca, S.A.) Makila 1A and Makila 1A1 model turboshaft engines.

**(d) Subject**

Joint Aircraft System Component (JASC) Code 7200, Engine (Turbine/Turboprop).

**(e) Unsafe Condition**

This AD was prompted by reports of false engine fire warnings. The FAA is issuing this AD to prevent false engine fire warnings. The unsafe condition, if not addressed, could lead to commanded in-flight engine shut-down, possibly resulting in damage to the helicopter and reduced control of the helicopter.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) Required Actions**

Except as specified in paragraphs (h) and (i) of this AD: Perform all required actions within the compliance times specified in, and in accordance with European Union Aviation Safety Agency (EASA) AD 2022–0244, dated December 8, 2022 (EASA AD 2022–0244).

**(h) Exceptions to EASA AD 2022–0244**

(1) Where EASA AD 2022–0244 requires compliance from its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the “Remarks” section of EASA AD 2022–0244.

(3) Although the service information referenced in EASA AD 2022–0244 specifies to discard any removed fire detectors, this AD requires removing those parts from service.

**(i) No Reporting Requirement**

Although the service information referenced in EASA AD 2022–0244 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

**(j) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD and email to: [ANE-AD-AMOC@faa.gov](mailto:ANE-AD-AMOC@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

**(k) Additional Information**

For more information about this AD, contact Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; email: [kevin.m.clark@faa.gov](mailto:kevin.m.clark@faa.gov).

**(l) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0244, dated December 8, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0244, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu). You may find this material on the EASA website at [ad.easa.europa.eu](http://ad.easa.europa.eu).

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District

Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

Issued on January 13, 2023.

**Gaetano A. Sciortino,**

*Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2023–01101 Filed 1–18–23; 11:15 am]

**BILLING CODE 4910–13–P**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**
**21 CFR Part 876**

[Docket No. FDA–2022–N–3255]

**Medical Devices; Gastroenterology-Urology Devices; Classification of the Computerized Behavioral Therapy Device for Treating Symptoms of Gastrointestinal Conditions**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is classifying the computerized behavioral therapy device for treating symptoms of gastrointestinal conditions into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the computerized behavioral therapy device for treating symptoms of gastrointestinal conditions’ classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices.

**DATES:** This order is effective January 20, 2023. The classification was applicable on November 25, 2020.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Cole, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2536, Silver Spring, MD 20993–0002, 301–796–8587, [Stephanie.Cole@fda.hhs.gov](mailto:Stephanie.Cole@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified the computerized behavioral therapy device for treating symptoms of gastrointestinal conditions as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).