

5 hours TIS, until the torque for all four tailboom attachment points has stabilized.

(6) Where paragraph C. of Transport Canada AD CF-2022-68 refers to "defect," this AD defines that as a crack, dent, loose fastener, unsecure attachment, deformation, or corrosion.

(7) Where paragraph C. of Transport Canada AD CF-2022-68 specifies to contact Bell Product Support Engineering for a repair or instructions to rectify any defect, this AD requires repair done in accordance with a method approved by the Manager, General Aviation & Rotorcraft Section, International Validation Branch, FAA; or Transport Canada; or Bell Textron Canada Ltd.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(8) Where the service information referenced in paragraph C. of Transport Canada AD CF-2022-68 specifies to discard parts, this AD requires removing those parts from service.

(9) Where paragraph D. of Transport Canada AD CF-2022-68 specifies to report inspection results to Bell Product Support Engineering within 30 days after accomplishing the inspections required by paragraphs A. or C., this AD requires reporting inspection results at the applicable time in paragraph (h)(9)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 10 days after accomplishing the actions required by paragraph A. or C. of Transport Canada AD CF-2022-68.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 10 days after the effective date of this AD.

(i) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199, provided no passengers are onboard.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: 9-AVS-AIR-730-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) Related Information

For more information about this AD, contact Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177;

telephone (817) 222-5110; email kristin.bradley@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 this AD specifies otherwise.

(i) Transport Canada AD CF-2022-68, dated December 15, 2022.

(ii) [Reserved]

(3) For Transport Canada AD CF-2022-68, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, CANADA; telephone 888-663-3639; email TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca; internet tc.canada.ca/en/aviation. You may find the Transport Canada material on the Transport Canada website at tc.canada.ca/en/aviation.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this material 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, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued on December 21, 2022.

Christina Underwood,

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

[FR Doc. 2022-28315 Filed 12-23-22; 11:15 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2022-1649; Project Identifier MCAI-2022-01206-E; Amendment 39-22284; AD 2022-26-05]

RIN 2120-AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc) Turbofan 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 Rolls-Royce Deutschland Ltd & Co KG (RRD) TAY 620-15 and TAY 650-15

model turbofan engines. This AD was prompted by reports of cracks on the high-pressure turbine (HPT) stage 2 intermediate air seal attachment bolts (attachment bolts). This AD requires repetitive inspections of the HPT stage 2 intermediate air seal and attachment bolts and, depending on the results of the inspections, replacement of attachment bolts and the HPT stage 1 and stage 2 rotor disks, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 12, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 12, 2023.

The FAA must receive comments on this AD by February 13, 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. 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 under Docket No. FAA-2022-1649; 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 material incorporated by reference in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@easa.europa.eu. You may find this material on the EASA website at 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.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer,

ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238-7241; email: Sungmo.D.Cho@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-2022-1649; Project Identifier MCAI-2022-01206-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 Sungmo Cho, 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 2022-0184, dated September 2, 2022 (EASA AD 2022-0184) (referred to after this as “the MCAI”), to correct an unsafe condition

for all RRD TAY 620-15 and TAY 650-15 model turboprop engines. The MCAI states that cracks on attachment bolts have been reported which, if not detected and corrected, could result in failure of HPT stage 1 and stage 2 rotor disks, high energy debris release, damage to the airplane, and reduced control of the airplane.

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

You may examine the MCAI in the AD docket under Docket No. FAA-2022-1649.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2022-0184, dated September 2, 2022, which specifies procedures for repetitive inspections of the HPT stage 2 intermediate air seal and attachment bolts and, depending on the findings, replacement of all damaged parts.

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 the State of Design Authority, it has notified the FAA of the unsafe condition referenced 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 the same type design.

AD Requirements

This AD requires accomplishing the actions specified in EASA AD 2022-0184, described previously, except for any differences identified as exceptions in the regulatory text of this AD and except as discussed under “Differences Between this AD and the MCAI.”

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 since coordinated with other manufacturers and CAAs to use this process. As a result, EASA AD 2022-0184 will be incorporated by reference in this final rule. This AD, therefore, requires compliance with

EASA AD 2022-0184 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 the EASA AD 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 2022-0184. Service information required by the EASA AD for compliance will be available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2022-1649.

Differences Between This AD and the MCAI

Where EASA AD 2022-0184 requires replacement of all damaged parts, this AD requires replacement of attachment bolts and the HPT stage 1 and stage 2 rotor disks.

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.

There are currently no domestic operators of these products. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason, 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

The requirements of the Regulatory Flexibility Act (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 notice and comment, RFA analysis is not required.

Costs of Compliance

Currently, there are no U.S. registered airplanes with the affected engines

installed. If an affected engine is installed on an airplane, or if an airplane with an affected engine is imported and placed on the U.S.

Register in the future, the FAA provides the following cost estimates to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive inspection of the HPT stage 2 intermediate air seal and attachment bolts.	3 work-hours × \$85 per hour = \$255	\$0	\$255	\$0

The FAA estimates the following costs to do any necessary replacements

that would be required based on the results of the inspection.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace attachment bolts and HPT stage 1 and stage 2 rotor disks.	6 work-hours × \$85 per hour = \$510	\$280,189	\$280,699

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:

2022–26–05 Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc): Amendment 39–22284; Docket No. FAA–2022–1649; Project Identifier MCAI–2022–01206–E.

(a) Effective Date

This airworthiness directive (AD) is effective January 12, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG TAY 620–15 and TAY 650–15 model turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7240, Turbine Engine Combustion Section.

(e) Unsafe Condition

This AD was prompted by reports of cracks on high-pressure turbine (HPT) stage 2 intermediate air seal attachment bolts (attachment bolts). The FAA is issuing this AD to prevent failure of the HPT stage 1 and stage 2 rotor disks. The unsafe condition, if not addressed, could result in high energy debris release, damage to the airplane, and reduced control of the airplane.

(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 2022–0184, dated September 2, 2022 (EASA AD 2022–0184).

(h) Exceptions to EASA AD 2022–0184

(1) Where EASA AD 2022–0184 requires compliance from its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2022–0184 requires replacement of all damaged parts, this AD requires replacing cracked attachment bolts and HPT stage 1 and stage 2 rotor disks that show evidence of wear from broken attachment bolts.

(3) Where the service information referenced in EASA AD 2022–0184 specifies to replace the engine and send the removed engine to an approved TAY overhaul facility if indications of damage are found, this AD requires replacing cracked attachment bolts and HPT stage 1 and stage 2 rotor disks that show evidence of wear from broken attachment bolts.

(4) This AD does not adopt the "Remarks" paragraph of EASA AD 2022–0184.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0184 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

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. 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 Sungmo Cho, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7241; email: Sungmo.D.Cho@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 AD 2022–0184, dated September 2, 2022.

(ii) [Reserved]

(3) For more information about EASA AD 2022–0184, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@easa.europa.eu. You may find this EASA AD on the EASA website at 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, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued on December 14, 2022.

Christina Underwood,

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

[FR Doc. 2022–28221 Filed 12–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 870**

[Docket No. FDA–2022–N–3185]

Medical Devices; Cardiovascular Devices; Classification of the Interventional Cardiovascular Implant Simulation Software Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency or we) is classifying the interventional cardiovascular implant simulation software device 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 interventional cardiovascular implant simulation software device's 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 December 28, 2022. The classification was applicable on September 8, 2021.

FOR FURTHER INFORMATION CONTACT: Judy Ji, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2543, Silver Spring, MD, 20993–0002, 301–796–6949, Judy.Ji@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Upon request, FDA has classified the interventional cardiovascular implant simulation software device 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).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for