months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2026–0041 is at the applicable limitations and associated thresholds as incorporated by the requirements of paragraph (3) of EASA AD 2026–0041.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2026–0041.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2026–0041.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2026–0041.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* 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 responsible Flight Standards 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 (n) of this AD and email to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Additional Information

For more information about this AD, contact Amanda Pieraccini, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7329; email: *9-AVS-AIR-BACO-COS@faa.gov*.

(o) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on October 16, 2026.

(i) European Union Aviation Safety Agency (EASA) AD 2026–0041, dated February 27, 2026.

(ii) [Reserved]

(4) The following material was approved for IBR on January 16, 2024 (88 FR 86029, December 12, 2023).

(i) European Union Aviation Safety Agency (EASA) AD 2023–0100, dated May 11, 2023.

(ii) [Reserved]

(5) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu*.

(6) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on August 31, 2026.

Paul R. Bernado,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–18601 Filed 9–10–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–2287; Project Identifier MCAI–2025–01208–E; Amendment 39–23459; AD 2026–18–04]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–06–16 for certain Rolls-Royce Deutschland Ltd & Co KG (RRD) Model RB211 Trent 768–60, 772–60, and 772B–60 engines. AD 2020–06–16 required initial and repetitive ultrasonic inspections (UIs) of the affected low-pressure compressor (LPC) blades and, depending on the results of the UIs, replacement with a part eligible for installation. Since the FAA issued AD 2020–06–16, RRD issued updated service material providing improvements to the ultrasonic inspection procedures and updated initial inspection compliance times. This AD requires initial and repetitive UIs of the affected LPC blades for sub-surface anomalies and, depending on the results of the UIs, replacement with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 16, 2026. The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 16, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–2287; 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 address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material 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* under Docket No. FAA–2026–2287.

FOR FURTHER INFORMATION CONTACT: Alexis Whitaker, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (516) 228–7309; email: *alexis.j.whitaker@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020–06–16, Amendment 39–19885 (85 FR 17738, March 31, 2020) (AD 2020–06–16). AD 2020–06–16 applied to certain RRD Model RB211 Trent 768–60, 772–60, and 772B–60 engines. AD 2020–06–16 required initial and repetitive UIs of the affected LPC blades and, depending on the results of the UIs, replacement with a part eligible for installation. The FAA

issued AD 2020–06–16 to prevent LPC blade airfoil separation.

The NPRM was published in the **Federal Register** on March 3, 2026 (91 FR 10349). The NPRM was prompted by EASA AD 2025–0144, dated July 9, 2025 (EASA AD 2025–0144) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that occurrences have been reported of LPC partial airfoil blade release events on RRD Model Trent 700 engines. The MCAI also states that RRD issued updated service material providing improvements to the ultrasonic inspection procedures and updated initial inspection compliance times.

In the NPRM, the FAA proposed to continue to require initial and repetitive UIs of the affected LPC blades for sub-surface anomalies and, depending on the results of the UIs, replacement with a part eligible for installation.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–2287.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters. Commenters included the Air Line Pilots Association, International (ALPA) and an anonymous commenter. ALPA supported the NPRM without change. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Clarify Reporting Requirement

An individual commenter requested that the FAA clarify why paragraph (i) of the proposed AD eliminates the manufacturer's reporting requirement, including identifying what specific data elements are collected under the EASA AD specifications and whether the data is used by RRD to monitor fleet-wide anomaly rates, refine inspection intervals, or update service instructions. The commenter stated that the NPRM removes the requirement to submit inspection findings to RRD but does not describe the content of that requirement or provide any reasoned explanation for its omission. The commenter also stated that if the reporting requirement supports fleet-level surveillance or service bulletin development, its omission would disrupt the data feedback loop and reduce the completeness of data available to the manufacturer. The commenter asserted that if the requirement does not serve these functions, the FAA should explicitly state as much.

The FAA disagrees with the request. The FAA normally requires reporting if the results are needed to determine the scope of the identified unsafe condition or to develop future corrective actions. For this AD, reporting is not necessary as the inspection and replacement of the LPC blade addresses the unsafe condition. Operators are encouraged to voluntarily submit data to RRD by normal processes. The FAA did not change this AD as a result of this comment.

Request To Clarify Effective Date Exception

An individual commenter requested that the FAA clarify why paragraph (h)(1) of the proposed AD substitutes the effective date of the FAA AD for all references to the effective date of EASA AD 2025–0144. The commenter stated that the FAA should not replace EASA AD effective dates with FAA AD effective dates without identifying how EASA AD 2025–0144 measures its compliance times, the resulting inspection deadlines under both effective dates, and whether any affected engines would operate longer before initial inspection under the FAA rule than under the EASA AD specifications. The commenter noted that compliance times are date-relative and substitution of the FAA AD effective date extends the initial inspection window for U.S.-registered engines relative to the EASA AD specifications. The commenter asserted that without this comparison, the record does not demonstrate that the proposed framework avoids a timing gap for a known blade release hazard or maintains equivalence with EASA's safety intent.

The FAA acknowledges the commenter's concerns and clarifies that FAA standard procedure is to reference the FAA AD effective date rather than the EASA AD effective date because applying the EASA effective date would impose retroactive compliance requirements and could place operators in immediate noncompliance upon issuance of the FAA AD. The use of the FAA AD effective date rather than the EASA AD effective date prevents grounding of airplanes that are above the threshold while still allowing for an acceptable level of safety. The FAA did not change this AD as a result of this comment.

Request To Clarify Retainment of Affected Part Numbers

An individual commenter requested that the FAA clarify whether part numbers FK25441, FK25968, FW11901, and FW15393, which were removed from the applicability of EASA AD 2025–0144, are currently installed on U.S.-registered engines and, if so, identify the estimated number of affected engines or parts. The commenter stated that if the FAA lacks current installation data at the part-number level, it should consult RRD service records or require operators to report current installation status as part of the initial compliance action, rather than imposing indefinite regulatory applicability on parts that may no longer be in service.

The FAA disagrees with request because the unsafe condition applies to part numbers FK25441, FK25968, FW11901, and FW15393, regardless of whether they are currently in service or not. The LPC blades are rotable parts that can be later installed in engines. The FAA did not change this AD as a result of this comment.

Conclusion

These products have been approved by the civil 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, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025–0144, which specifies procedures for performing an ultrasonic inspection of the LPC blade for sub-surface anomalies, and replacement, if necessary.

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 the **ADDRESSES** section.

Differences Between This AD and the MCAI

Where EASA AD 2025–0144 applies to RRD Model RB211 Trent 772C–60 engines, this AD does not, as these engines do not have an FAA type certificate.

Where EASA AD 2025–0144 removes LPC part numbers FK25441, FK25968,

FW11901, and FW15393 from the affected parts list, this AD includes these part numbers in the applicability in the event that any of these parts remain in service.

Costs of Compliance

The FAA estimates that this AD affects 140 engines installed on airplanes 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
Inspect LPC blade	37 work-hours × $85 per hour = $3,145	$0	$3,145	$440,300

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the inspection. The agency has no way of determining the number of engines that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace one LPC blade	6 work-hours × $85 per hour = $510	$225,000	$225,510

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,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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:

■ a. Removing Airworthiness Directive 2020–06–16, Amendment 39–19885 (85 FR 17738, March 31, 2020); and

■ b. Adding the following new airworthiness directive:

2026–18–04 Rolls-Royce Deutschland Ltd & Co KG: Amendment 39–23459; Docket No. FAA–2026–2287; Project Identifier MCAI–2025–01208–E.

(a) Effective Date

This airworthiness directive (AD) is effective October 16, 2026.

(b) Affected ADs

This AD replaces AD 2020–06–16, Amendment 39–19885 (85 FR 17738, March 31, 2020).

(c) Applicability

This AD applies to all Rolls-Royce Deutschland Ltd & Co KG (RRD) Model RB211 Trent 768–60, 772–60, and 772B–60 engines, with a low-pressure compressor (LPC) blade having part number (P/N) FK23411, FK25441, FK25968, FW11901, FW15393, FW23643, FW23741, FW23744, KH23403, KH23404, or LV11570, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by reports of LPC partial airfoil blade release events. The FAA is issuing this AD to prevent LPC blade airfoil separation. The unsafe condition, if not addressed, could result in engine nose cowl loss, under cowl fires, forward projection of secondary debris, damage to the engine, damage to the airplane, and injury to persons on the ground.

(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 2025–0144, dated July 9, 2025 (EASA AD 2025–0144).

(h) Exceptions to EASA AD 2025–0144

(1) Where EASA AD 2025–0144 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where the Groups definition in EASA AD 2025–0144 specifies ''NMSB'', this AD requires replacing that text with ''RR Alert NMSB RB.211–72–AL191, Initial Issue, dated May 30, 2025''.

(3) Where the definition of an affected part in EASA AD 2025–0144 specifies ''Part Number (P/N) FK23411, FW23643, FW23741,

FW23744, KH23403, KH23404 or P/N LV11570'', this AD requires replacing that text with ''P/N FK23411, FW23643, FW23741, FW23744, FK25441, FK25968, FW11901, FW15393, KH23403, KH23404, or LV11570, installed''.

(4) This AD does not adopt the ''Remarks'' paragraph of EASA AD 2025–0144.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2025–0144 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety 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 AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *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 Alexis Whitaker, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (516) 228–7309; email: *alexis.j.whitaker@faa.gov*.

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2025–0144, dated July 9, 2025.

(ii) [Reserved]

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

(4) You may view this material 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 material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on August 28, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–18559 Filed 9–10–26; 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–2026–N–9907]

Medical Devices; Cardiovascular Devices; Classification of the Cardiovascular Machine Learning-Based Notification Software

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the cardiovascular machine learning-based notification software 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 classification of the cardiovascular machine learning-based notification software. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective September 11, 2026. The classification was applicable on August 3, 2023.

FOR FURTHER INFORMATION CONTACT: Hetal Odobasic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2108, Silver Spring, MD 20993–0002, 240–402–6540, *Hetal.Odobasic@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the cardiovascular machine learning-based notification software into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 (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 (see also part 860, subpart D (21 CFR part 860, subpart D)). 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 classification 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 premarket notification (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