(v) A means must be available, in the event of failure of the airplane's main power system, or of the normal stairway lighting system, for emergency illumination to be automatically provided in the stairway.

(1) This emergency illumination must be independent of the main lighting system.

(2) The sources of general illumination may be common to both the emergency and the main lighting systems if the power supply to the emergency lighting system is independent of the power supply to the main lighting system.

(3) Emergency illumination must be provided so that, when measured along the centerlines of each tread and landing, the illumination is not less than 0.05 foot-candles.

Issued in in Kansas City, Missouri, on June 4, 2025.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2025–10837 Filed 6–12–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–1101; Project Identifier MCAI–2025–00616–Q; Amendment 39–23060; AD 2025–12–02]

RIN 2120–AA64

Airworthiness Directives; Ipeco Holdings Limited Pilot and Co-Pilot Seats

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Ipeco Holdings Limited (Ipeco) pilot and co-pilot seats. This AD was prompted by reports of unexpected rearward movement of pilot and co-pilot seats during take-off and landing. This AD requires a one-time visual inspection of each affected seat, accomplishment of applicable corrective actions, and operational tests. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 30, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 30, 2025.

The FAA must receive comments on this AD by July 28, 2025.

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–2025–1101; 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 Ipeco material identified in this AD, contact Ipeco Holdings Limited, Aviation Way, Southend on Sea, SS2 6UN, United Kingdom; phone: +44 1702 545118; fax: +44 1702 540782; email: *technicalsupport@ipeco.com.*
- 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. It is also available at *regulations.gov* under Docket No. FAA–2025–1101.

FOR FURTHER INFORMATION CONTACT: Brenda Buitrago Perez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–288–7368; email *9-AVS-AIR-BACO-COS@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this final rule. Send your comments using a method listed under the **ADDRESSES** section. Include ''Docket No. FAA–2025–1101; Project Identifier MCAI–2025–00616–Q'' 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,* 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 Brenda Buitrago Perez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–288–7368; email *brenda.l.buitrago.perez@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The Civil Aviation Authority (CAA), which is the aviation authority for the United Kingdom (UK), has issued UK CAA AD G–2025–0002, dated April 11, 2025; corrected April 25, 2025 (UK CAA AD G–2025–0002) (also referred to as the MCAI), to correct an unsafe condition on certain Ipeco pilot and co-pilot seats. The MCAI states that occurrences were reported of unexpected rearward movement of pilot and co-pilot seats during take-off and landing. Investigations originally determined that horizontal guide block wear, presence of burrs on horizontal center track, and horizontal track lock system weakness (spring tension too low) were causes which contributed to the seat not being correctly locked. The original unsafe condition was addressed through UK CAA AD G–2022–0011, dated June 9, 2022, (which corresponds with FAA AD 2023–14–10, Amendment 39–22510, dated August 3, 2023 (88 FR 51230) (FAA AD 2023–14–10)). However, the incorrect distribution of

the stops and packers during the modification required by FAA AD 2023–14–10 has been found to cause the seat not to positively lock in position because of the unequal re-installation of the stops and packers onto the fore/aft tubes during seat reassembly, which can result in unexpected rearward movement of pilot and co-pilot seats during take-off and landing.

The FAA is issuing this AD to address the unsafe condition on these products, which, if not corrected, could lead to further cases of unwanted flight crew seat movement, which could result in reduced control of the airplane, a rapid descent of the airplane, and serious injury to passengers and crew. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–1101.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Ipeco Service Bulletin 063–25–20, Issue 1, dated March 25, 2025. This material describes procedures to conduct a one-time visual inspection of each affected seat, and if any incorrect installation is found (stops or packers), remove and install the stops and packers, and perform operational tests of the seats. 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.

FAA's Determination

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 and material referenced 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 the Ipeco material described previously. See ''Differences Between This AD and the MCAI'' for a discussion of the general differences included in this AD.

Differences Between This AD and the MCAI

UK CAA AD G–2025–0002, dated April 11, 2025; corrected April 25, 2025, does not mention Part C of the Accomplishment Instructions of Ipeco Service Bulletin 063–25–20, Issue 1, dated March 25, 2025. This AD, however, requires the accomplishment of Part C of the Accomplishment Instructions of Ipeco Service Bulletin 063–25–20, Issue 1, dated March 25, 2025. The FAA has coordinated this change with the UK CAA.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(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 forgoing notice and comment prior to adoption of this rule because movement of the pilot and co-pilot seats during take-off and landing could result in reduced control of the airplane, a rapid descent of the airplane, and serious injury to passengers and crew. Additionally, the compliance time in this AD is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(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 forgo 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 prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 120 appliances installed on, but not limited to, ATR–GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = $170	$0	$170	$20,400

The FAA estimates the following costs to do any necessary on-condition action that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × $85 per hour = $85	$420	$505

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:

2025–12–02 Ipeco Holdings Limited: Amendment 39–23060; Docket No. FAA–2025–1101; Project Identifier MCAI–2025–00616–Q.

(a) Effective Date

This airworthiness directive (AD) is effective June 30, 2025.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to Ipeco Holdings Limited (Ipeco) pilot and co-pilot seats, identified by series part number in figure 1 to paragraph (c)(1) of this AD.

FIGURE 1 TO PARAGRAPH (c)(1)—AFFECTED SEATS

Pilot seat	Co-pilot seat
3A063–0033–( )–( )	3A063–0034–( )–( )
3A063–0035–( )–( )	3A063–0036–( )–( )
3A063–0037–( )–( )	3A063–0038–( )–( )
3A063–0079–( )–( )	3A063–0080–( )–( )
3A063–0099–( )–( )	3A063–0100–( )–( )

(2) These pilot and co-pilot seats are known to be installed on, but not limited to, ATR–GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Reason

This AD was prompted by reports of unexpected rearward movement of pilot and co-pilot seats during take-off and landing. The FAA is issuing this AD to address unexpected movement of pilot and co-pilot seats on takeoff and landing. The unsafe condition, if not addressed, could result in reduced control of the airplane, a rapid descent of the airplane, and serious injury to passengers and crew.

(f) Compliance

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

(g) Inspection and Replacement of Stops and Packers

(1) Within 3 months after the effective date of this AD, inspect all affected seats which have been modified by Ipeco Service Bulletin 063–25–15; Ipeco Service Bulletin 063–25–16; Ipeco Service Bulletin 063–25–17; or Ipeco Service Bulletin 063–25–18. Do the inspection in accordance with Part A of the Accomplishment Instructions of Ipeco Service Bulletin 063–25–20, Issue 1, dated March 25, 2025.

(2) If, during the inspection as required by paragraph (g)(1) of this AD, correct installation of the stops and packers is found, before further flight, perform the operational tests, in accordance with Part C of the Accomplishment Instructions of Ipeco Service Bulletin 063–25–20, Issue 1, dated March 25, 2025.

(3) If, during the inspection as required by paragraph (g)(1) of this AD, any incorrect installation of the stops or packers is found, before further flight, remove and install the stops and packers and perform operational tests, in accordance with Part B and Part C of the Accomplishment Instructions of Ipeco Service Bulletin 063–25–20, Issue 1, dated March 25, 2025.

(h) Special Flight Permits

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(i) 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, or the attention of the person identified in paragraph (j) of this AD, 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 the UK CAA; or Ipeco Holdings Limited's UK CAA Alternative Procedures to Design Organization Approval (ADOA). If approved by the ADOA, the approval must include the ADOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Brenda Buitrago Perez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–288–7368; email *9-AVS-AIR-BACO-COS@faa.gov.*

(k) 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.

(i) Ipeco Service Bulletin 063–25–20, Issue 1, dated March 25, 2025.

(ii) [Reserved]

(3) For Ipeco material identified in this AD, contact Ipeco Holdings Limited, Aviation Way, Southend on Sea, SS2 6UN, United Kingdom; phone: +44 1702 545118; fax: +44 1702 540782; email: *technicalsupport@ipeco.com.*

(4) 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.

(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 June 10, 2025.

Christopher R. Parker,

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

[FR Doc. 2025–10823 Filed 6–10–25; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2025–N–1503]

Medical Devices; Immunology and Microbiology Devices; Classification of the Cellular Analysis System for Multiplexed Antimicrobial Susceptibility Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the cellular analysis system for multiplexed antimicrobial susceptibility testing 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 cellular analysis system for multiplexed antimicrobial susceptibility testing'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, in part by reducing regulatory burdens.

DATES: This order is effective June 13, 2025. The classification was applicable on February 23, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the cellular analysis system for multiplexed antimicrobial susceptibility testing 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 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 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). 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 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 (21 U.S.C. 360c(a)(1)). Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On July 14, 2016, FDA received Accelerate Diagnostics, Inc.'s request for De Novo classification of the Accelerate PhenoTest BC Kit. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 23, 2017, FDA issued an order to the requestor classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21