DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	4/8/2026-4/16/2026* FEI NUMBER 1221084

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Troas T. Walling, President

FIRM NAME	STREET ADDRESS
Permobil Inc	300 Duke Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lebanon, TN 37090-8115	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been adequately applied.

Specifically,

Your firm is a contract manufacturer of Class II medical devices such as powered wheelchairs including the Permobil M3 and M5 and the SmartDrive Wheelchair Power Assist. Your firm also performs distribution and complaint handling functions for these devices. Your firm has not adequately documented the appropriate processes needed for the quality management system to include adequately applying risk control measures to control nonconforming products, documenting change control, analyzing quality data feedback, and performing corrective and preventive actions. For example:

A. Your firm does not adequately apply risk-based controls to nonconforming products. Your procedure SOP0084 defines (b) (4) severity as (b) (4) (b) (4) However, your firm incorrectly classified nonconformance records involving loose bolts on safety-critical components as (b) (4) severity. Additionally, two open nonconformances from 5/20/2025 (NCR-09353 and NCR-09354) were classified as (b) (4) severity despite being associated with an ongoing field action (GR7357) for a drive inhibit defect that created a fall/tip hazard.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jamie P Webb, Investigator X Jamie P Webb Investigator Signed By: 2003424907 Date Signed: 04-16-2026 13:03:39	4/16/2026

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B. Your firm's change control process does not adequately assess risk or verify that changes made to correct device malfunctions are effective. Engineering Change Notice (ECN) 01-00305 covers all Power Platform software/firmware updates affecting M3 and M5 wheelchairs. ECN 01-00305 Version 13 (dated 3/7/2024) was updated to correct a drive inhibit malfunction in M3 wheelchairs. Approximately one year later, the same drive inhibit malfunction was identified in M5 wheelchairs and was corrected in ECN 01-00305 Version 31 (dated 5/22/2025). Verification testing is not performed at your site to confirm software changes are adequately implemented in your firm's production, and your firm's change control process failed to prevent recurrence of the same malfunction in other wheelchair models.

C. Your firm has not adequately applied risk-based controls to quality data feedback. For example, your procedure WI0579 (Review Feedback for Complaints) requires designated personnel to review customer feedback to make complaint determinations. However, Feedback received 9/12/2025 described a wheelchair falling into a pool requiring fire department intervention, and a feedback received 10/21/2025 described a wheelchair being hit by an automobile. Neither feedback was identified as a complaint and no investigations were performed to determine if device malfunctions occurred.

D. Your firm's Corrective and Preventive Action process does not adequately demonstrate that your firm is correcting and preventing (b) (4) risk quality issues within your firm's control. For example, CAPA 24-004 (initiated 2/23/2024) does not contain corrective actions to address your firm's failure to identify nonconforming products prior to distribution. This failure recurred when CAPA GR7342 (initiated 5/21/2025) documented the same type of drive inhibit malfunction affecting M5 wheelchairs, which has resulted in an ongoing field correction.

OBSERVATION 2

Production and service provision was not adequately planned, carried out, monitored, and controlled to ensure that product conforms to specification.

Specifically,

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Your firm failed to ensure that the production process included adequate objective and measurable product requirements for powered wheelchairs contract manufactured by your firm, including the Permobil M3, an electric mid-wheel drive wheelchair for outdoor and indoor driving intended for people with physical disabilities were adequately documented and that ongoing monitoring methods of the production process were effective.

A. Your firm does not perform adequate final inspections to verify finished product conforms to specifications. For example,
   a. Your firm's final inspection procedures do not include objective measures to verify software features such as safety-critical speed restriction requirements for powered wheelchairs. As evidenced by your firm distributing malfunctioning M3 and M5 Corpus wheelchairs with a speed restriction defect that created a fall/tip-over hazard.
   b. Your firm's final inspection process does not include adequate measures to verify that finished powered wheelchairs meet assembly requirements. As evidenced by complaints documenting loose hardware.

B. Your firm does not perform adequate in-process inspections to verify that critical assembly requirements are met during production. Your firm implemented corrective actions under CAPA 25-017 in November 2025 to address calibration and torque control measures during production. However, nonconformance records demonstrate that in-process controls remain inadequate to prevent loose hardware from progressing through production to final inspection.

***DATES OF INSPECTION**
4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."