

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139		DATE(S) OF INSPECTION 2/2/2026-2/5/2026 FEI NUMBER 1821729			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Michael F. LaBrake, Director of Customer Service and Quality					
FIRM NAME Amigo Mobility International, Inc.		STREET ADDRESS 6693 Dixie Hwy			
CITY, STATE, ZIP CODE, COUNTRY Bridgeport, MI 48722-9725		TYPE ESTABLISHMENT INSPECTED Medical Device			
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. <i>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.</i>					
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 One or more processes for risk management in product realization have not been adequately documented. Specifically, Your firm has not adequately documented the risk management process for identifying hazards, harms, and risk control measures associated with the use and design of your class II Amigo Mobility Scooters (Models: HD, RD, RT, and Escort 7.5). FMEAs reviewed during the inspection were either incomplete or missing. For example, the FMEA for the RT model does not exist. Additionally, your firm has not established a documented process to ensure that risk management files are updated based on postmarket surveillance data, and that newly identified or increased risks trigger reassessment and implementation of additional controls as necessary. For example, two complaints from 2024 (Complaint (b) (4) and (b) (4)) involved users not being able to stop the Amigo RD Scooter. However, the FMEA for the RD model has not been updated since 3/2/99 and does not address this hazardous situation, its expected occurrence, or associated risk mitigation measures.					
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; padding: 5px;"> EMPLOYEE(S) SIGNATURE David J Gasparovich, Investigator </td> <td style="width: 40%; padding: 5px; vertical-align: bottom;"> David J Gasparovich Investigator Signed By: DAVID GASPAROVICH-J Date signed: 02-05-2026 15:50:56 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE David J Gasparovich, Investigator	David J Gasparovich Investigator Signed By: DAVID GASPAROVICH-J Date signed: 02-05-2026 15:50:56 X
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OBSERVATION 2

Corrective action procedures defining the requirements for determining the causes of nonconformities and reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically,

Your *Root Cause Analysis and CAPA* procedure (QP-131; Rev. G; Effective Date: 12/5/22) has not been adequately implemented to determine the root cause of nonconformities as required per Section 4.0.

For example, Corrective Action #216 was initiated because the Design Control procedure was not followed during ECN 220610. The Root Cause Analysis field states, "*QP-109 'Design Control' needs to be reviewed and corrected. After approval of the document - all engineers will need to be trained to the new Revision.*" This statement identifies corrective actions but does not identify why the procedure was not followed or what underlying cause led to the nonconformity. Section 4.3 of QP-131 requires the investigator to uncover the root cause of the problem, which was not established. Corrective Action #216 was closed as effective on 2/21/23.

Additionally, QP-131 has not been adequately implemented to measure and assess the effectiveness of corrective actions as required per Section 4.6. For example, the verification of effectiveness field for Corrective Action #216 states, "*Verification of effectiveness will be monitored during normal internal audit process.*" This statement does not define what specific activities, metrics, or acceptance criteria will be used to verify the corrective action's effectiveness, making it impossible to objectively determine whether the implemented solution has been effective.

OBSERVATION 3

Nonconforming product was not adequately evaluated to determine the need for an investigation and notification of any external party responsible for the nonconformity.

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Specifically,

Your (b) (4) nonconformance system lacks a documented mechanism for determining and recording whether an investigation is required following a nonconformance event, as required by Section 4.2 of procedure *Control of Nonconforming Product* (QP-126; Rev. J, Effective 5/10/25). For example, NCR-3307 documented the following nonconformity: (b) (4)

(b) (4)
(b) (4) M.L., Director of Service and Quality, explained that whoever created the print used a tolerance for (b) (4) steel when they should have been using a tolerance for (b) (4) steel. Review of this NCR revealed no documented evaluation of whether this nonconformance warranted investigation. The system does not provide a field, checkbox, or other mechanism to capture this required determination.

Your nonconformance system does not include a documented mechanism to demonstrate that responsible persons or organizations are notified of nonconformities, as required by Section 4.2 of procedure *Control of Nonconforming Product* (QP-126; Rev. J, Effective 5/10/25).

OBSERVATION 4

Process(es) for establishing competence, providing needed training and ensuring personnel awareness have not been adequately documented.

Specifically,

Your firm has not implemented the *Competence and Training* procedure (QP-104; Rev. E; Effective Date: 5/31/26), which establishes guidelines and assigns responsibilities for identifying training needs, providing training, and maintaining training records.

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Instead, personnel competence is tracked using a (b) (4) that employs an internal numbering system to assess employee proficiency. (b) (4) and its associated numbering system are not defined, referenced, or controlled by any documented procedure. Additionally, no records of employee training were available upon request.

OBSERVATION 5

Procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements were not adequately documented.

Specifically,

Your *Measuring and Monitoring Equipment* procedure (QP-121; Rev. D; Effective Date: 6/19/23) does not adequately document a process to ensure that monitoring and measuring equipment is removed from use or otherwise controlled once it has exceeded its calibration due date.

Your Calibration Log demonstrated that the (b) (4) was identified being past its calibration due date. On 2/4/26, I requested to visually see the (b) (4) to understand how it was being stored and maintained. However, management was unable to immediately locate this piece of equipment, demonstrating the absence of an established process for identifying, segregating, and controlling equipment that has exceeded its calibration interval.

OBSERVATION 6

The selection of auditors and conduct of audits did not adequately ensure objectivity and impartiality of the audit.

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Specifically,

Your firm failed to ensure that internal auditors do not audit areas for which they have direct responsibility, as required by Section 2.1 of procedure *Internal Quality Audits* (QP-123; Rev. G & H; Effective Date: 11/7/22 - Present). For example, during your 2024 and 2025 internal quality audits, (b) (6), (b) (7)(C) Quality Coordinator, audited the complaint handling process despite having direct responsibility for this area.

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Annotations to Observations

Observation 1: Not annotated
 Observation 2: Not annotated
 Observation 3: Not annotated
 Observation 4: Not annotated
 Observation 5: Not annotated
 Observation 6: Not annotated

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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."