DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	2/24/2026-3/27/2026* FEI NUMBER 3010392999

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emma K Fauss, PhD, Chief Executive Officer (CEO)

FIRM NAME	STREET ADDRESS
Medical Informatics Corp.	7255 Helix Park Ave (Suite 1b
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77030-1321	Software 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.

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,

According to your firm's Product Risk Management Procedure (DC-002), a risk management plan must be documented for all Medical Informatics Corp (MIC) products. Implementation and effectiveness of each risk control measure must be verified and recorded in the risk management file.

Your Sickbay Clinical Platform is a remote monitoring software that displays physiologic data, waveforms and alarms routed through the Sickbay Clinical Platform for supported devices, intended to route & store medical device data and diagnostic information. It also incorporates (b) (4) applications which require Sickbay Clinical Platform data to run.

Your Head of Legal & Compliance was asked to provide the risk management plans, as well as the risk analysis for the Sickbay Clinical Platform and its (b) (4) applications, as required by your Product Risk Management Procedure (DC-002).

However,

A review of the data provided for the Sickbay Clinical Platform showed that

- The Sickbay Clinical Platform's Risk Analysis Table incorporates risk control measures. However, according to your Head of Legal & Compliance, there is no documentation to show that these risk control measures were verified.

A review of the data provided for the (b) (4) - Sickbay Clinical Platform applications showed that:

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- 07/(b) (4) Sickbay applications, which include applications that allow the user to view cardiac waveform, monitor patient adverse events, score risk and calculate mortality risk, have incomplete or inadequate product risk or hazard analysis (i.e., they fail to address the possible harm to the patient);
- 07/(b) (4) Sickbay applications, which include applications that display emergency alarms, alarm statistics, monitor alarms on all connected devices at a single or multiple patient's bedside and determine bed group assignment, had no risk management plan or product risk/hazard analysis;
- None of the Sickbay applications, which include applications that display vital signs, cardiac activity and provide alarms, have documented evidence of verification of the risk control measures.

Risk management control has not been established by Medical Informatics Corp (MIC).

OBSERVATION 2

Design and development procedures were not adequately documented.

Specifically, your firm failed to address all requirements of the Design Control procedure (DC-001) which defines the life cycle process required for planning, development, production, verification, validation and transfer of new or significantly modified Medical Informatics Corp. (MIC) products.

For example,

(a) Your firm's Design Control procedure (DC-001) fails to address design outputs, or software specifications. As such, design outputs were not created, for the SickBay Clinical Platform (510K # K143304, 05/26/20215), nor its (b) (4) new applications, referencing acceptance criteria, prior to verification, to address the proper functioning of the device, i. e. essential design outputs, prior to their release for distribution. According to your Director of Informatics, your firm used the results of the verification as "acceptance criteria". (ISO 13485:2016, CLAUSE 7.3.4)

(b) Your firm's Design Control procedure (DC-001) fails to address the transfer of design and development outputs to manufacturing to ensure that design and development outputs are verified as suitable for manufacturing, prior to becoming final production specifications.

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The SickBay Clinical Platform, with its (b) (4) applications (dated 2015 – 2025), were released without an adequate design transfer process in place. (ISO 13485:2016, CLAUSE 7.3.8)

(c)Your firm's Design Control procedure (DC-001) fails to accurately address how your firm handles design changes.

According to your Head of Legal & Compliance, your firm's design change process is documented in the Design Control procedure (DC-001) as an Iterative Design Review (IDR). Per the Design Control procedure (DC-001), the legal department must review if additional regulatory action is required prior to product release, i.e. changes to intended use.

Your Head of Legal & Compliance was unable to provide documented evidence that this regulatory review was conducted prior to the release. (ISO 13485:2016, CLAUSE 7.3.9)

OBSERVATION 3

The specific approach and activities associated with the revalidation of software used in production and service provision were not proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Specifically,

Your firm's Software Product Verification & Validation Procedure (TEC-005) fails to address your firm's approach and the activities involved with conducting a revalidation of software; to ensure it is proportionate to the risk associated with your Sickbay Clinical Platform software.

For example,

The version of the Sickbay Clinical Platform reviewed was Version 3.45.

According to the data provided by your Head of Legal & Compliance, Sickbay version 3.45 has had

- (b) (4) hotfix software updates
  (A nonconformance impacting the software product's quality, functionality, or usability and must

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be resolved in the most current version before the next minor release.) and

- (b) (4) emergency patches
  (A critical nonconformance requiring immediate action due to significant impact on the product's quality, functionality, or usability. The fix is limited to resolving the specific cause of the malfunction only.)

According to your Lead Technical Product Manager, regression testing is not done after software bugs are resolved.

The lack of regression testing and MDR, "Near Misses" documented, for possibly interfaced code, was not evaluated to determine if a revalidation of the software was required.

OBSERVATION 4
Written MDR procedures have not been maintained.

Specifically,

Your firm's MDR procedure (COM-008), documents that all Complaint tickets will be evaluated by the Director of Compliance and Chief Technology Officer to determine whether to initiate an adverse event investigation.

However, your firm has not adequately evaluated complaints for MDR reportability in the past 02 years.

According to your Head of Legal & Compliance & staff, only 08 of the current 1146 complaints or ~6/10th of 1 %, have initiated review for MDR reportability.

Additionally, your Director of Compliance was unable to provide documentation that Medical Informatics Corp has registered for an eMDR account with FDA.

OBSERVATION 5
Corrective action procedures defining the requirements for reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically,

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Your firm's Corrective and Preventive Action System Policy & Procedure (COM-007) documents that CAPA approvers will confirm the plan for CAPA verification is linked to Action task(s) and evaluate applicability of the actions taken in appropriately addressing the issue and the root cause to prevent recurrence. Verification will be conducted after actions taken have been implemented and significant time has passed to evaluate effectiveness of those actions

However,

Verifications of effectiveness were not adequate to prevent recurrence.

For example,

(a) Your firm was originally made aware that your risk analysis for the Sickbay Clinical Platform was incomplete after your 2019- FDA inspection.

- CAPA 20220321 was opened to address Risk Analysis on 03/21/2022 and closed 02/19/2025.
- CAPA 2 opened to address Risk Analysis on 12/26/2023 and closed on 05/13/2024.
- Your current FDA audit (2026) indicates your firm has not created an adequate risk analysis for the Sickbay Clinical Platform and its (b) (4) applications.

(b) Your firm was originally made aware that your Sickbay Clinical Platform and applications did not have Design outputs by your 2020 -ISO 13485 audit.

- However, the current FDA inspection finds that your firm continues to lack design outputs or specifications, establishing the acceptance criteria for testing & verification, of your Sickbay clinical Platform and its (b) (4) applications.

(c) Your firm was originally made aware that the supplier evaluation process at Medical Informatics Corp was incomplete after a 2021- ISO 13485 audit.

- CAPA 20211026 opened to address supplier qualification on 10/26/2021 and closed 12/27/2022.
- CAPA 5 was opened to address the requirements for suppliers on 12/27/2023 and closed 10/02/2025.

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- Your current FDA audit (2026) indicates your firm continues to lack monitoring and evaluation of suppliers.

Recurrence of these nonconformances documents that your firm failed to verify that the corrective actions taken did not adversely affect the ability to meet regulatory requirements or the safety and performance of the medical device.

OBSERVATION 6

The monitoring and re-evaluation of suppliers was not planned.

Specifically,

According to your Purchasing procedure, Quality System Supplier Qualification Procedure (COM-001), Critical suppliers must be evaluated (b) (4) while non-critical suppliers must be followed up with every (b) (4) using the Supplier Evaluation Form (xxx-xxxx-xxx). The Supplier Evaluation Form must be completed by the Director of Compliance Officer, or their designee.

However, according to your Head of Legal & Compliance, none of the suppliers on the Approved Supplier List were monitored.

For example,

There are (b) (4) documented suppliers on the Approved Supplier List, in which 13/(b) (4) are critical suppliers who provide information crucial to the proper functioning of the SickBay Clinical Platform and 02/(b) (4) are non-critical.

According to the head of Legal & Compliance, the Supplier Evaluation form had not been completed by the Director of Compliance for the critical suppliers (b) (4) including suppliers that provide software library management, cybersecurity, contractors and perform code analysis,since initial approval to the Medical Informatics Corp - Approved Supplier List.

Your firm has failed to adequately monitor and evaluate suppliers of raw material and outsourced processes according to risk.

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OBSERVATION 7

The output from management review did not adequately include the input reviewed and any decisions and actions related to improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes.

Specifically,

The Management Responsibility procedure (QS-009) documents that based on information presented at the Management Review meeting attendees must note actions and/or corrective actions to address identified problems. These actions must be documented in the meeting minutes. Corrective actions initiated from the Management Review meeting will have its origin identified on the corrective action report (COM-007).

(b) (4) Reports presented for Management Review must include the following specific reports:

a. Quality System Objectives Table
b. Last (b) (4) Audit Results
c. **Open Corrective Action Reports**
d. (b) (4) Products Availability Report (up/down time)
e. (b) (4) Maintenance Log

However, per your Director of Compliance, outputs for the Management Review, or open Corrective Actions, are documented in (b) (4) sent solely to upper management and not documented in the Management Review Meeting minutes, for internal audit review.

***DATES OF INSPECTION**

2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri), 3/02/2026(Mon), 3/03/2026(Tue), 3/04/2026(Wed), 3/27/2026(Fri)

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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

Observation 7: 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."