DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William H. Shoop, CEO

FIRM NAME	STREET ADDRESS
3B Medical, Inc.	5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dublin, OH 43017-7537	Medical Device 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

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, your firm's complaint and incident handling procedures including the following procedures:

- SP.QA.0011 "Customer Complaints" rev I, dated 06/27/25 (and previous revisions rev H (dated 12/5/2024), and rev G (dated 8/27/2024))
- SP.QA.0013 "Incident Reporting Procedure" rev I, dated 06/27/25 (and previous revisions rev H (dated 12/05/2024), and rev G (dated 12/05/2024))

do not ensure that complaints received by your firm are adequately handled. For example,

A) Your firm's complaint procedures do not ensure that there is enough information requested when possible medical complications occur. For example, in 3 out of 11 complaints reviewed where no MDR had been filed and some concerns about injury are suggested. This includes:
   a. CN-011887 dated 1/31/2025 for a Luna G3 APAP states "that the machine shuts off in the middle of the night […] chokes her out and she is afraid to use it". There is no additional information about whether medical complications occurred

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rosanna M Goodrich, Medical Device Specialist X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich -S Date Signed: 12-10-2025 15:46:30	12/10/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William H. Shoop, CEO	
FIRM NAME 3B Medical, Inc.	STREET ADDRESS 5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

documented in the complaint. No MDR was filed.

b. CN-026089 dated 7/24/2025 for a Luna G3 APAP, states "that in the middle of therapy the device will suddenly send burst of hard rapid airflow that wakes him and makes him short of breath". There is no additional information about whether medical complications occurred documented in the complaint. No MDR was filed.

c. CN-014116, dated 2/21/2025, for a Luna G3 APAP, states that the "device not auto adjusting, pt woke up short of air, device not tracking." There is no additional information about whether medical complications occurred documented in the complaint. No MDR was filed.

B) Your complaint handling procedure does not ensure that all investigations completed and documented in the Returned Merchandise Authorization (RMA) tickets are added into the complaint file. For example, 3 complaints were noted to have complaint investigation but were still open. According to your Senior Complaint Manager (b) (6), (b) (7)(C) your firm was unaware that there was complaint investigations completed and not updating into your complaint system. Therefore, the complaints remain open. These investigations include the following:

a. CN-001449 dated 9/23/2024 was opened for error code message 77 Flow sensor issue of a Luna G3 APAP. The complaint was investigated on or around 2/24/2025 but the complaint file has not been updated.

b. CN-004426 dated 10/31/2024 was opened for pulsating when blowing of a Luna G3 APAP. The complaint was investigated on or around 1/14/2025 but the complaint file has not been updated.

c. CN-025871 dated 7/24/2025 was opened for pressure fluctuating of a Luna G3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rosanna M Goodrich, Medical Device Specialist X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich -S Date Signed: 12-10-2025 15:46:30	12/10/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William H. Shoop, CEO	
FIRM NAME 3B Medical, Inc.	STREET ADDRESS 5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

APAP. The complaint was investigated on or around 7/30/2025 but the complaint file has not been updated.

C) Your firm's procedures do not ensure that all complaints are considered complaints and therefor ensure they are evaluated, investigated and reviewed as possible MDRs. For example,

a. 9 out of 11 complaints reviewed which were cancelled by your firm, appear to be complaints. For example,
   i. CN-029335, dated 9/20/2025, was initiated due "outer box damage". Your firm cancelled the complaint because it was related to shipping damage.

   ii. CN-030142, dated 10/3/2025, was initiated due to the patient dropping the machine and it stopped working. Your firm cancelled the complaint and stated that it was not a complaint because it was dropped.

b. 13 out of 15 inquires reviewed appeared to be complaints. For example,
   i. INQ-26292, dated 8/18/2025, was initiated due to machine turning over on the nightstand causing water to flow back into the machine, and now the machine fluctuates heavily and constantly. This was deemed not a complaint due to the patient damage.

   ii. INQ-24107, dated 10/27/2025, was initiated due to the button on the machine is broken. It was deemed not a complaint because the button was not in warranty.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rosanna M Goodrich, Medical Device Specialist X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich -S Date Signed: 12-10-2025 15:46:30	12/10/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William H. Shoop, CEO	
FIRM NAME 3B Medical, Inc.	STREET ADDRESS 5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

Procedures for corrective and preventive action have not been adequately established.

Specifically, your following procedures:

- SP.QA.0012 “Corrective and Preventive Action (CAPA) Procedure,” rev E dated 6/27/25 (and previous revision rev D (7/12/2023))
- SP.SC.0007 “Supplier Corrective Action Procedure” rev B, dated 11/15/2024
- SP.QA.0035 “Quality Data Trending,” rev C, dated 10/29/24
- SP.QA.0029 “Statistical Techniques Procedure,” rev C, dated 11/12/24
- SP.QA/0035.F1 “Matrix, Quality Data Metrics” rev D, dated 10/29/24

does not ensure that your CAPA system and the data leading into your CAPA system is adequate. For example,

A.) Your procedures do not ensure that CAPAs initiated by your firm are adequately handled. For example,

b. Your procedure does not ensure that your CAPA identified and contained all product and or locations that might be affected. For example, in 1 out of 3 CAPAs reviewed, your firm did not include all possible containment locations.

> CAPA2408, dated 11/25/2024, was initiated due to expired product being shipped to your customer on or around 11/11/2024. The containment activities include (b) (out of (b) (4) possible warehouses that could receive product. Your firm did not consider the other (b) (4) warehouses and ensure that they were also unable to ship product that is past it’s expiration date

b. Your procedure requires that a CAPA is initiated when a field action is initiated. According to your Manager of Quality systems and Compliance (RRP), CAPA2408, dated 11/25/2024, was opened in part to control the field action initiated by your firm on or around November 25, 2024. There is no mention of the field action in the CAPA record.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rosanna M Goodrich, Medical Device Specialist X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich -S Date Signed: 12-10-2025 15:46:30	12/10/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William H. Shoop, CEO	
FIRM NAME 3B Medical, Inc.	STREET ADDRESS 5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

B.) Your statistical analysis on complaints received by your firm is inadequate. For example,

a. Statistical analysis on devices cleared under different 510(k)s are reviewed together. For example, Luna 2 and Luna 3 are looped together as a single device category in complaint quality reviews even though they are 2 different 510(k)s and 5 different models.

b. Your procedures do not define when a CAPA will be initiated for complaints quality review. For example, according to your (b) (4) quality data review dated June 18, 2025, "Pressure Fluctuation continues to be the top Event Type for CPAPs" and no CAPA or SCAR has been initiated.

c. Your firm's complaint by event type in the Matrix is reviewed by "customer reported" issue at the time of complaint receipt. There is no data analysis review for the investigated issues. Your firm is responsible for conducting complaint investigations.

OBSERVATION 3

The importer failed to submit a report to the manufacturer within (b) (4) concerning information that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, your firm's complaint and incident handling procedures including the following procedures:

- SP.QA.0011 "Customer Complaints" rev I, dated 06/27/25 (and previous revisions rev H (dated 12/5/2024), and rev G (dated 8/27/2024))
- SP.QA.0013 "Incident Reporting Procedure" rev I, dated 06/27/25 (and previous

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William H. Shoop, CEO	
FIRM NAME 3B Medical, Inc.	STREET ADDRESS 5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

revisions rev H (dated 12/05/2024), and rev G (dated 12/05/2024))

Does not ensure that information on potential malfunctions are reported to the manufacturer within (b) (4) ensuring that potential malfunctions MDRs are being reported within timeframes to the FDA. For example,

On 8/1/2025, your firm became aware of a LUNA G3 BPAP that was having low pressure issues and caused a hospital admission. This complaint was documented via CN-026567 and an MDR was filed. Since then, your firm has not added "low pressure" to the list of malfunctions that are sent to the Luna's device manufacturer as a potential reportable malfunction. Your firm has received 42 complaints for Luna devices since 8/8/2025 where the complainant event type is "low pressure". This includes
CN-032779, dated 11/12/2025, for the Luna G3 BPAP which states that the "bipap powers up but the air flow is minimal".

OBSERVATION 4
Risk analysis is inadequate and is incomplete.

Specifically, your procedure SP.QA.0025, "Risk Management Process" rev C, dated 03/27/23, has not ensured that the risk management report for iCode Connect is updated as required. The most recent risk management report, version V1.1, which was initiated by your supplier, and which was unsigned and dated 2016.8.30. The risk management report was not reviewed and updated to include design changes such as:

A.) New CPAP devices became available for use with iCode Connect. This includes:

- Luna G2 APAP in October 2018
- Luna G3 APAP in January 2022
- Luna G3 25A Bilevel in January 2022
- Luna G3 30VT BiPap in February 2023 and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rosanna M Goodrich, Medical Device Specialist X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich -S Date Signed: 12-10-2025 15:46:30	12/10/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William H. Shoop, CEO	
FIRM NAME 3B Medical, Inc.	STREET ADDRESS 5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

- G3 X APAP in July 2025.

B.) According to your Chief Technology Officer (b) (6), (b) (7)(C) a refactored version of the iCodeConnect code base was released in July 2024.

OBSERVATION 5

The design history file does not demonstrate that the design was developed following the approved design plan.

Specifically, your firm's design procedures including:

- Doc ID 3B-DCP-0002 “Design Control Process”, rev 01 dated 8/11/2019
- SOP-900032 “Product Development Process software as a Medical Device (SaMD)” rev A, dated 08/04/25.

As well as Watermark Medical procedure PD-2011 “Design Change Procedure” rev 04, undated,
does not ensure that design history files are maintained.

A list of design history files associated with the iCode Connect was included as part of the “Software Copyright Transfer Contract” which is dated May 8, 2025. Your firm does not have access to all versions of these documents including the Risk Management Report (document number YF-CSP1-3-02) versions 2.0, 3.0 and 4.0. The only copy your firm has available is version 1.1.

OBSERVATION 6

Procedures for training and identifying training needs have not been adequately established.

Specifically, SP.HR.0004 “Training and Competency Procedure” rev C dated 06/28/24 (and previous revision B, dated 5/13/22)) does not ensure that your employees are adequately

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025* FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William H. Shoop, CEO	
FIRM NAME 3B Medical, Inc.	STREET ADDRESS 5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

trained. For example,

Your procedures require that there is a documented effectiveness check on training. 3 out of [(b)( ] training effectiveness checks for employees who conduct complaint handling and incident reporting has not been completed.

Furthermore, during discussion regarding complaint's being cancelled and other complaint handling observations, your Manager of Quality Systems and Compliance (RRP) stated that it was due to your ex-employee [(b) (6), (b) (7)]. This ex-employee was responsible for the classroom training for all [(b) (4)] current complaint handling employees.

OBSERVATION 7

Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system at defined intervals.

Specifically, procedure SP.QA.0015, "Management Review Procedure," rev C, dated 12/22/23, does not ensure that management with executive responsibility, specifically the CEO or COO, is included in management reviews.

Your firm's CEO was not present during the management review in either 2024 or 2025 and your COO was not present in 2025.

*DATES OF INSPECTION

12/01/2025(Mon), 12/02/2025(Tue), 12/03/2025(Wed), 12/04/2025(Thu), 12/05/2025(Fri), 12/08/2025(Mon), 12/10/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rosanna M Goodrich, Medical Device Specialist	X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich -S Date Signed: 12-10-2025 15:46:30	12/10/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/1/2025-12/10/2025*
	FEI NUMBER 3009096682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William H. Shoop, CEO

FIRM NAME	STREET ADDRESS
3B Medical, Inc.	5475 Rings Rd Ste 550
CITY, STATE, ZIP CODE, COUNTRY Dublin, OH 43017-7537	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rosanna M Goodrich, Medical Device Specialist X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich -S Date Signed: 12-10-2025 15:46:30	12/10/2025

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."