**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<br>Cincinnati, OH 45202<br>(513)322-0700 Fax:(513)679-2772 | 6/23/2026-6/29/2026*<br>FEI NUMBER<br>3011089437 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Bradley Stroka, Senior Quality and HSE Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| TT Electronics | 3700 Lane Rd Ext |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Perry, OH 44081-9563 | contract 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

One or more processes for risk management in product realization have not been adequately documented.

Specifically, your "Risk Management Procedure," Rev 07, dated 6/30/2025, "Hazard Identification, Risk Assessment & Control", Issue 13, dated 10/7/2024, and FMEA, #60006708-1004, Rev C, dated 2/23/2026, lacks clarity, contains contradictory information and does not clearly define your risk management process. For example:

(a)Risk controls are not consistently or adequately documented within your FMEA. Of the 163-line items documenting "*Requirements and Potential Failure Modes*" only three (3) included additional risk controls, and none of those three had documentation confirming implementation. The remaining 160-line items indicated that no further action was required.

(b)Process controls identified in your FMEA are insufficiently specific, preventing confirmation that risks are adequately mitigated. Examples of vague risk controls listed include: *"Operator negligence/oversight," "receiving inspection," "training visual," "in-process warning,"* and *"work instructions."*.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Laureen M Geniusz, Investigator<br>X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-29-2026 13:36:47 | 6/29/2026 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 550 Main Street, Ste 4-930<br>Cincinnati, OH 45202<br>(513)322-0700 Fax:(513)679-2772 | 6/23/2026-6/29/2026*<br>FEI NUMBER<br>3011089437 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Bradley Stroka, Senior Quality and HSE Manager | |
| FIRM NAME<br>TT Electronics | STREET ADDRESS<br>3700 Lane Rd Ext |
| CITY, STATE, ZIP CODE, COUNTRY<br>Perry, OH 44081-9563 | TYPE ESTABLISHMENT INSPECTED<br>contract medical device manufacturer |

(c)Significant revisions have been made to your FMEA without documented rationale. For example:

Risk Row #121: AC power cable installed incorrectly.
FMEA, Rev. dated 11/4/2024 (no Rev. letter): Severity (b)(4) Detection (b)(4) RPN = (b)(4)
FMEA, Revision dated 2/23/2026 (Rev C): Severity (b)(4) Detection (b)(4) RPN = (b)(4)

The associated hazard ((b) (4) ) is identical across both versions; however, the severity rating decreased from (b)(4) to (b)(4) without explanation. According to your FMEA, severity ratings with a (b)(4) or (b)(4) require risk reduction. There was no documented risk reduction.

(d)The risk scoring methodology used in the PFMEA is not consistent with the risk scoring methodology established in procedure #QP18/01-01 (Issue 13) for Hazard Identification, Risk Assessment & Control. Specifically, the PFMEA uses a (b) (4) with action thresholds reaching into the hundreds, while procedure #18/01-01 prescribes a (b) (4) model (b) (4) ) with a maximum possible RPN of (b)(4) and a mitigation target of (b)(4) or less. Your Risk Management procedure refers to a (b) (4) - (b) (4) RPN. It is unclear when risk reduction is required.

## OBSERVATION 2

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

Your post-market data, including complaints, non-conformances, and quality issues/notices, has neither been defined nor incorporated into updates to your FMEA.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Laureen M Geniusz, Investigator | X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-29-2026 13:36:47 | 6/29/2026 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 550 Main Street, Ste 4-930<br>Cincinnati, OH 45202<br>(513)322-0700 Fax:(513)679-2772 | 6/23/2026-6/29/2026*<br>FEI NUMBER<br>3011089437 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bradley Stroka, Senior Quality and HSE Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| TT Electronics | 3700 Lane Rd Ext |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Perry, OH 44081-9563 | contract medical device manufacturer |

**OBSERVATION 3**

Requirements for infrastructure maintenance activities that can affect product quality, including the interval of performing the maintenance activities, have not been adequately documented.

Specifically, your procedure covering maintenance activities, "Operation and Scheduled Maintenance/Repair of Machines/Equipment", #QP7/1-02, issue #35, dated 10/10/2025, lacks sufficient clarity regarding the documentation, review, and assessment of unplanned maintenance activities. Additionally, the procedure does not adequately address how to determine whether such maintenance activities could potentially impact a validated process, including processes such as (b) (4) (b) (4) or(b) (4) .

**OBSERVATION 4**

Records of corrective actions, including the results of any investigations and actions taken, were not adequately maintained.

Specifically, during your performance qualification of the PCBA process, PQ-CAH0031, dated 2/6/2026, an assembly issue was identified and Corrective action #1592 was subsequently assigned. However, this corrective action was inadvertently deleted and was never formally opened per "Corrective Action Request (CAR) Procedure", Issue 44, dated 7/23/2025. Despite this, the final report concluded that verification was complete, acceptance criteria were met, and any non-conformances encountered during the build had been corrected.

***DATES OF INSPECTION**

6/23/2026(Tue), 6/24/2026(Wed), 6/25/2026(Thu), 6/26/2026(Fri), 6/29/2026(Mon)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Laureen M Geniusz, Investigator | X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-29-2026 13:36:47 | 6/29/2026 |

**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<br>Cincinnati, OH 45202<br>(513)322-0700 Fax:(513)679-2772 | 6/23/2026-6/29/2026*<br>FEI NUMBER<br>3011089437 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Bradley Stroka, Senior Quality and HSE Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| TT Electronics | 3700 Lane Rd Ext |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Perry, OH 44081-9563 | contract medical device manufacturer |

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Laureen M Geniusz, Investigator

X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-29-2026 13:36:47

DATE ISSUED

6/29/2026

**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<br>Cincinnati, OH 45202<br>(513)322-0700 Fax:(513)679-2772 | 6/23/2026-6/29/2026* |
| | FEI NUMBER<br>3011089437 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bradley Stroka, Senior Quality and HSE Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| TT Electronics | 3700 Lane Rd Ext |
| CITY, STATE, ZIP CODE, COUNTRY<br>Perry, OH 44081-9563 | TYPE ESTABLISHMENT INSPECTED<br>contract 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

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Laureen M Geniusz, Investigator<br>X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-29-2026 13:36:47 | 6/29/2026 |

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."