

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715		DATE(S) OF INSPECTION 3/17/2025-3/20/2025 FEI NUMBER 3005737891	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Andreas Schochtel, Managing Director			
FIRM NAME Thermo Electron LED GmbH		STREET ADDRESS Robert-Bosch-Str. 1	
CITY, STATE, ZIP CODE, COUNTRY Langenselbold, Hesse, 63505 Germany		TYPE ESTABLISHMENT INSPECTED 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.			
<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 Products that do not conform to specifications are not adequately controlled. Specifically, non conformance records do not include documentation of the rework and retest of effected product. For example, non conformance (b)(4) opened due to the failed calibration of measuring (b)(4). The record indicates that the non conformance was attributed to a mounting failure. There is no documentation in the non conformance record of the repair or rework and the retesting of the reworked product. Also, non conformance record (b)(4) was opened because the failed calibration of measuring cell (b)(4). The non conformance record identifies that incorrect parameters were found in the MZ tester. It was explained that the non conformance was attributed to the PCB of the measuring cell. Documentation of the reason for the non conformance, the rework and retest of the board was not found in the non conformance record.			
OBSERVATION 2 Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established. Specifically, the firm is using Global procedure SOP 0009168 for supplier selection, evaluation, approval and monitoring. (b)(4) has been supplying solenoid valves for			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Stephen D Eich, Investigator - Dedicated Device Cadre		DATE ISSUED 3/20/2025 Stephen D Eich Investigator - Dedicated Device Cadre Signed By: Stephen D. Eich -S Date Signed: 03-20-2025 1624-48 X

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Annotations to Observations Observation 1: Not annotated Observation 2: 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."