DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	2/2/2026-2/5/2026* FEI NUMBER 3006059109

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert B. Schock, Vice President of Research and Development

FIRM NAME	STREET ADDRESS
Life Recovery Systems HD, LLC	170 Kinnelon Rd Ste 8
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kinnelon, NJ 07405-2347	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 firm's *Thermosuit Risk Analysis*, Ver A, Eff. 6/28/2022, *Thermosuit Risk Analysis*, Ver. Q, Eff. 6/28/2022, *Risk Management Policy (LRS-114),* Ver D, Eff. 6/7/2022, and *Risk Management Plan*, Ver. A, Eff. 06/02/2022, have not been adequately implemented. The risk procedures do not adequately evaluate the risks associated with the Thermosuit device. Your *Risk Management Plan*, Ver. A, Eff. 06/02/2022, defines (b) (4)
(b) (4)
(b) (4) Notably,

1. Your firm's *ThermoSuit Risk Analysis*, Ver. Q, Eff. 6/28/2022, lists (b) (4)
(b) (4) For example,

1.a. Line-item H.1.h documents the potential Hazard mode of (b) (4)
(b) (4)
(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jaro P Perera, Investigator X Jaro P Perera Investigator Signed By: 2004371194 Date Signed: 02-05-2026 11:23:00	2/5/2026

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(b) (4) as per section 6.2 of *Risk Management Plan*, Ver. A, Eff. 06/02/2022.

1.b.Line-item H.1.m documents the potential Hazard mode of (b) (4)
(b) (4)
(b) (4) as per section 6.2 of *Risk Management Plan*, Ver. A, Eff. 06/02/2022.

1.c.Line-item H.3.a documents the potential Hazard mode of (b) (4)
(b) (4)
(b) (4) as per section 6.2 of *Risk Management Plan*, Ver. A, Eff. 06/02/2022.

2.Your firm's *Thermosuit Risk Analysis*, Ver. Q, Eff. 6/28/2022, lists (b) (4)
(b) (4)
(b) (4) For example,

2.a.Line-item H.1.u documents the potential Hazard mode of (b) (4)
(b) (4)

2.b.Line-item H.1.r documents the potential Hazard mode of (b) (4)
(b) (4)

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X Jaro P Perera
Investigator
Signed By: 2004371194
Date Signed: 02-05-2026
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2.c.Line-item H.1.l documents the potential Hazard mode of (b) (4)
(b) (4)

OBSERVATION 2

The extent of verification activities for purchased product was not proportionate to the risks associated with the purchased product.

Specifically, your firm's *Acceptance Activities (LRS-115)*, Ver. G, Eff. 10/16/2019, does not ensure temperature monitoring probes will be evaluated for temperature accuracy. Your firm conducts incoming inspections of patient temperature monitoring probes which do not include verifying the accuracy of the probes. Your firm's management stated that they completed an (b) (4) assessment of the probe accuracy when approving the supplier in 2022 and have not verified the accuracy of any purchased probes since. Your firm implemented the temperature probe change on 1/17/2023. Your firm's risk documentation indicated the potential hazard of (b) (4) has the possible cause of (b) (4)
(b) (4) Your firm has manufactured (b) (4) ThermoSuit units, which each contain one temperature probe, with the temperature probes since January 17th, 2023.

***DATES OF INSPECTION**

2/02/2026(Mon), 2/03/2026(Tue), 2/05/2026(Thu)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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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."