STATE OF RHODE ISLAND DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

OFFICE OF COMPLIANCE & INSPECTION

IN RE: Confluent Medical Technologies, Inc FILE NO.: OCI-HW-20-23

NOTICE OF VIOLATION

A. INTRODUCTION

Pursuant to Sections 42-17.1-2(21) and 42-17.6-3 of the Rhode Island General Laws, as amended, ("R.I. Gen. Laws") you are hereby notified that the Director of the Rhode Island Department of Environmental Management ("Director" of "RIDEM") has reasonable grounds to believe that the above-named party ("Respondent") has violated certain statutes and/or administrative regulations under RIDEM's jurisdiction.

B. <u>ADMINISTRATIVE HISTORY</u>

On 13 February 2020, RIDEM inspected the facility that is the subject of this Notice of Violation ("NOV"). The inspection revealed many of the same violations that are the subject of the NOV. RIDEM's inspector spoke with Respondent's representative at the time of the inspection and advised the representative of the violations. As of the date of the NOV, Respondent has not demonstrated that it has corrected all the violations cited in the NOV.

C. FACTS

- (1) The facility is located at 80 Commerce Drive in Warwick, Rhode Island ("Facility"). The Facility manufactures woven or braided specialty textile/fabric products using synthetic fibers for medical applications such as sutures, heart valves, stints, and fiber screens.
- (2) Respondent operates the Facility.
- (3) Respondent is registered with RIDEM as a large quantity hazardous waste generator at the Facility pursuant to Rhode Island's *Rules and Regulations for Hazardous Waste Management* (250-RICR-140-10-1) ("HW Rules") and pursuant to Title 40 of the Code of Federal Regulations ("40 CFR") under the name of "Confluent Medical Technologies Inc." with the U.S. Environmental Protection Agency identification number RIR000508440.

- (4) On 13 February 2020 and 12 November 2021, RIDEM inspected the Facility. The inspection on 12 November 2021 revealed the following:
 - (a) Fifteen 14-gallon yellow plastic satellite containers were not labeled. Six containers held spent Acetone wipes, and nine containers held spent Isopropyl Alcohol ("IPA") wipes. One was stored in the QA Lab, one in CME #1, one in CME #2, one in CME #3, one in CME #4, one in CME #5, one in CME #6, four in CME #7, two in CME #10 and two in Building #2.
 - (b) Two 5-gallon black steel satellite containers were open, one was not labeled, and the other one had an incomplete label (i.e., the words "Hazardous Waste" were not on the label). Both contained spent acetone and/or spent IPA. One had a red funnel in the top, one had a white funnel. One container was stored in CME #1, and one was stored in CME #3.
 - (c) One 3-gallon red plastic satellite container was not labeled. It held spent acetone. It was stored in the QA Lab.
 - (d) Two 5-gallon white plastic satellite containers were open and had incomplete labels. Both held spent mixed waste of spent Acetone/IPA. Both had red funnels in the top. One was stored in CME #7, and one was stored in CME #10.
 - (e) One 5-gallon black plastic satellite container was open and not labeled. It held spent Acetone/IPA. It had a yellow funnel in the top. It was stored in Building #2.
 - (f) Four 55-gallon accumulation containers were not stored with secondary containment. Two were blue plastic, and two were black steel. One black steel container and one blue steel container also were not marked with an accumulation start date. All held IPA and Hexane. All were stored in the Shipping/Receiving Area.
 - (g) No adequate personnel training for employees that manage hazardous waste. Review of the two documents provided to RIDEM's inspectors at the time of the inspection ("Training Plan") revealed that the training program was missing the following required elements: A description of hazardous wastes, waste management procedures, container labeling, accumulation time limits, satellite and central accumulation requirements, and manifest documents. In addition, there was no indication of an annual review of the training in the documents provided.
 - (h) An incomplete hazardous waste contingency plan ("Contingency Plan") for the Facility. Review of an Emergency Action Plan ("EAP") provided to RIDEM's inspectors at the time of the inspection revealed that it was missing the following required elements: a description of arrangements made with local response authorities, a list of emergency coordinators, a list of emergency equipment, a description of procedures to assist outside response agencies and procedures taken to comply with 40 CFR 265.56. In addition, there was no

indication that the company has submitted the contingency plan to the local hospital and response agencies. On 19 November 2021, Respondent sent electronic correspondence to RIDEM with an attached document titled *Hazardous Waste Management and Contingency Plan, Rev 1*. Review of this plan, which is not dated but was reported to RIDEM as under development at the time of the inspection, reveals that the plan contains most of the items that were missing from the EAP. It is still missing a list of employees designated to act as emergency coordinators, the arrangements made with local response agencies and verification that the new plan was submitted to the local hospital and response agencies.

- (5) On 19 November 2021, Respondent submitted a Training Plan and Contingency Plan that complied with the HW Rules.
- (6) As of the date of the NOV, Respondent has failed to correct the noncompliance identified in subsection C (4)(a) through (f) above.

D. VIOLATION

Based on the foregoing facts, the Director has reasonable grounds to believe that you have violated the following statutes and/or regulations:

(1) HW Rules

- (a) Part 1.7.8(A)(1) requiring that a hazardous waste generator label all satellite accumulation containers holding hazardous waste with the words "Hazardous Waste" and chemical or common name of the waste.
- (b) Part 1.7.8(A)(4) requiring that a hazardous waste generator keep closed all satellite containers holding hazardous waste, except for when adding or removing waste.
- (c) Part 1.7.12(C)(1)(a) requiring that a hazardous waste generator mark containers holding hazardous waste with the date upon which the waste first began to accumulate.
- (d) Part 1.7.12(C)(1)(k) requiring that a hazardous waste generator provide a containment system for all drums and containers holding liquid hazardous waste in storage onsite.
- (e) Part 1.7.12(J)(1) (including Part 1.7.12(J)(1)(a), (b), (d), (e) and (j)) requiring that a hazardous waste generator provide training to company employees who handle and/or manage hazardous waste, provide employees with a review of the training on an annual basis and maintain a compliant written training program on-site that includes all the elements required by the regulation.

(f) Part 1.7.12(K)(1) (including Part 1.7.8(K)(1)(b), (c), (d), (f), (h)(3), (h)(8))—
requiring that a hazardous waste generator prepare and maintain a contingency
plan designed to minimize hazards to human health or the environment from
fires, explosions or unplanned releases of hazardous waste or constituents to the
air, soil, or surface water, which plan shall include all the elements required by
the regulation and be provided to local response agencies.

E. ORDER

Based upon the violations alleged above and pursuant to R.I. Gen. Laws Section 42-17.1-2(21), you are hereby ORDERED to **IMMEDIATELY upon receipt of the NOV**:

- (1) Label all satellite accumulation containers holding hazardous waste with the words "Hazardous Waste" and other words identifying the contents of the container.
- (2) Close all satellite accumulation containers holding hazardous waste and keep closed except for when adding or removing waste.
- (3) Mark all containers holding hazardous waste, excluding satellite accumulation containers, with the date upon which the hazardous waste first began to accumulate.
- (4) Provide secondary containment for all containers holding liquid hazardous waste. The containment system must be designed to contain spills and releases of the hazardous waste stored onsite.

F. PENALTY

(1) Pursuant to R.I. Gen. Laws Section 42-17.6-2, the following administrative penalty, as more specifically described in the attached penalty summary and worksheets, is hereby ASSESSED, jointly and severally, against each named respondent:

\$23,750

- (2) The proposed administrative penalty is calculated pursuant to Rhode Island's *Rules* and *Regulations for Assessment of Administrative Penalties* (250-RICR-130-00-1) ("Penalty Regulations") and must be paid to RIDEM within 30 days of your receipt of the NOV.
- (3) Penalty payments shall be by one of two methods:
 - (a) By certified check, cashier's check, or money order made payable to the General Treasury Environmental Response Fund and forwarded to:

Administrator, RIDEM Office of Compliance and Inspection 235 Promenade Street, Suite 220 Providence, RI 02908-5767

(b) By wire transfer in accordance with instructions provided by RIDEM.

- (4) Penalties assessed against Respondent in the NOV are penalties payable to and for the benefit of the State of Rhode Island and are not compensation for actual pecuniary loss.
- (5) If any violation alleged herein shall continue, then each day during which the violation occurs or continues shall constitute a separate offense and the penalties and/or costs for that violation shall continue to accrue in the manner set forth in the attached penalty summary and worksheets. The accrual of additional penalties and costs shall be suspended if the Director determines that reasonable efforts have been made to comply promptly with the NOV.

G. RIGHT TO ADMINISTRATIVE HEARING

- (1) Pursuant to R.I. Gen. Laws Chapters 42-17.1, 42-17.6, 42-17.7 and 42-35, each named respondent is entitled to request a hearing before RIDEM's Administrative Adjudication Division regarding the allegations, orders and/or penalties set forth in Paragraphs B through F above. All requests for hearing MUST:
 - (a) Be in writing. <u>See</u> R.I. Gen. Laws Sections 42-17.1-2(21)(i) and 42-17.6-4(b).
 - (b) Be **RECEIVED** by RIDEM's Administrative Adjudication Division, at the following address, within 20 days of your receipt of the NOV. <u>See</u> R.I. Gen. Laws Sections 42-17.1-2(21)(i) and 42-17.7-9:

Administrative Clerk
RIDEM - Administrative Adjudication Division
235 Promenade Street, Room 350
Providence, RI 02908-5767

- (c) Indicate whether you deny the alleged violations and/or whether you believe that the administrative penalty is excessive. See R.I. Gen. Laws Section 42-17.6-4(b).
- (d) State clearly and concisely the specific issues which are in dispute, the facts in support thereof and the relief sought or involved, if any. See Part 1.7(B) of Rhode Island's *Rules and Regulations for the Administrative Adjudication Division* (250-RICR-10-00-1).
- (2) A copy of each request for hearing must also be forwarded to:

Jenna Giguere, Esquire RIDEM - Office of Legal Services 235 Promenade Street, 4TH Floor Providence, RI 02908-5767

(3) Each named respondent has the right to be represented by legal counsel at all administrative proceedings relating to this matter.

- (4) Each respondent must file a separate and timely request for an administrative hearing before RIDEM's Administrative Adjudication Division as to each violation alleged in the written NOV. If any respondent fails to request a hearing in the above-described time or manner regarding any violation set forth herein, then the NOV shall automatically become a Final Compliance Order enforceable in Superior Court as to that respondent and/or violation and any associated administrative penalty proposed in the NOV shall be final as to that respondent. See R.I. Gen. Laws Sections 42-17.1-2(21)(i) and (vi) and 42-17.6-4(b) and (c).
- (5) Failure to comply with the NOV may subject each respondent to additional civil and/or criminal penalties.
- (6) The NOV does not preclude the Director from taking any additional enforcement action nor does it preclude any other local, state, or federal governmental entities from initiating enforcement actions based on the acts or omissions described herein.

If you have any legal questions, you may contact (or if you are represented by an attorney, please have your attorney contact) Jenna Giguere of RIDEM's Office of Legal Services at (401) 222-6607 ext. 2772306or at jenna.giguere@dem.ri.gov. All other inquiries should be directed to Tracey Tyrrell of RIDEM's Office of Compliance and Inspection at (401) 222-1360 ext. 2777407 or at tracey.tyrrell@dem.ri.gov.

Please be advised that any such inquiries do not postpone, eliminate, or otherwise extend the need for a timely submittal of a written request for a hearing, as described in Section G above.

FOR THE DIRECTOR

By:
Dated:

CERTIFICATION

I hereby certify the the within Notice of Viol	at on the day of ation was forwarded to:	
	Confluent Medical Technologies, Inc. c/o Corporation Service Company, Registered Agent 222 Jefferson Boulevard, Suite 200 Warwick, Rhode Island 02888	
by Certified Mail.		



ADMINISTRATIVE PENALTY SUMMARY

Program: Hazardous Waste File No.: OCI-HW-20-23

Respondent: Confluent Medical Technologies, Inc.

GRAVITY OF VIOLATION

SEE ATTACHED "PENALTY MATRIX WORKSHEETS."

SEE ATTACHED "PENALTY MATRIX WORKSHEETS."					
VIOLATION No. & CITATION	APPLICATION O	F MATRIX	RIX PENALTY CALCULATION		AMOUNT
	Туре	Deviation	Penalty from Matrix	Number or Duration of Violations	
D (1)(a) – Satellite container labeling	Type I (\$ <u>25,000</u> Max. Penalty) *	Moderate	\$12,500	1 violation	\$12,500
D (1)(b) – Satellite containers closed	Type I (\$ <u>25,000</u> Max. Penalty) *	Minor	\$6,250	1 violation	\$6,250
D (1)(c) – Accumulation start date	Type I (\$ <u>25,000</u> Max. Penalty) *	Minor	\$2,500	1 violation	\$2,500
D (1)(d) – Secondary containment	Type I (\$ <u>25,000</u> Max. Penalty) *	Minor	\$2,500	1 violation	\$2,500
SUB-TOTAL					\$23,750

^{*}Maximum Penalties represent the maximum penalty amounts per day, per violation.

ECONOMIC BENEFIT FROM NONCOMPLIANCE

COSTS OF COMPLIANCE, EQUIPMENT, O&M, STUDIES OR OTHER DELAYED OR AVOIDED COSTS, INCLUDING INTEREST AND/OR ANY COMPETITIVE ADVANTAGE DERIVED OVER ENTITIES THAT COMPLY. NOTE: ECONOMIC BENEFIT MUST BE INCLUDED IN THE PENALTY UNLESS:

- THERE IS NO IDENTIFIABLE BENEFIT FROM NONCOMPLIANCE, OR
- THE AMOUNT OF ECONOMIC BENEFIT CAN NOT BE QUANTIFIED.

A review of the record in this matter has revealed that Respondent has either enjoyed no identifiable benefit from the noncompliance alleged in this enforcement action or that the amount of economic benefit that may have resulted cannot be quantified.

ADMINISTRATIVE PENALTY SUMMARY (continued)

COST RECOVERY

ADDITIONAL OR EXTRAORDINARY COSTS INCURRED BY THE DIRECTOR DURING THE INVESTIGATION, ENFORCEMENT AND RESOLUTION OF AN ENFORCEMENT ACTION (EXCLUDING NON-OVERTIME PERSONNEL COSTS), FOR WHICH THE STATE IS NOT OTHERWISE REIMBURSED.

A review of the record in this matter has revealed that RIDEM has not incurred any additional or extraordinary costs during the investigation, enforcement, and resolution of this enforcement action (excluding non-overtime personnel costs), for which the State is not otherwise reimbursed.

TOTAL PENALTY PROPOSED UNDER PENALTY REGULATIONS = \$23,750

PENALTY MATRIX WORKSHEET

CITATION: Satellite container labeling

VIOLATION NO.: D (1)(a)

ТҮРЕ					
X TYPE I DIRECTLY related to protecting health, safety, welfare, or environment.	TYPE II INDIRECTLY related to protecting health, safety, welfare, or environment.	TYPE III INCIDENTAL to protecting health, safety, welfare, or environment.			

DEVIATION FROM THE STANDARD

THE DEGREE TO WHICH A PARTICULAR VIOLATION IS OUT OF COMPLIANCE WITH THE REQUIREMENT VIOLATED.

FACTORS CONSIDERED:

Taken from Part 1.10(A)(1)(b) of the Penalty Regulations.

- (1) The extent to which the act or failure to act was out of compliance: Respondent failed to label satellite containers holding hazardous waste. The requirement to label containers holding hazardous waste is an integral part of the regulatory program because this requirement reduces the potential for mismanagement of hazardous waste. Proper labeling of hazardous waste containers provides important information regarding the chemical properties of the waste for emergency responders who may be called to a facility during a fire, spill, or release.
- (2) Environmental conditions: Considered, but not utilized for this calculation.
- (3) Amount of the pollutant: Fifteen 14-gallon containers, four 5-gallon containers and one 3-gallon container were not labeled in accordance with the HW Rules.
- (4) **Toxicity or nature of the pollutant**: All of the containers held spent Acetone and/or Acetone/IPA wipes. Acetone is a highly flammable liquid that has a flashpoint of 0°F, and IPA has a flashpoint of 53°F.
- (5) **Duration of the violation**: Unknown.
- (6) Areal extent of the violation: Considered, but not utilized for this calculation.

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- (7) Whether the person took reasonable and appropriate steps to prevent and/or mitigate the noncompliance: Respondent failed to take reasonable and appropriate steps to prevent the noncompliance by properly labeling the containers. The noncompliance was previously documented in an inspection by RIDEM on 13 February 2020 and Respondent was advised of the noncompliance at the time of the inspection. RIDEM has no information of what steps, if any, Respondent has taken to mitigate the noncompliance.
- (8) Whether the person has previously failed to comply with any regulations, order, statute, license, permit, or approval issued or adopted by the Department, or any law which the Department has the authority or responsibility to enforce: Considered, but not utilized for this calculation.
- (9) The degree of willfulness or negligence, including but not limited to, how much control the violator had over the occurrence of the violation and whether the violation was foreseeable: Respondent had complete control over the occurrence of the violation and failed to take steps to prevent the occurrence.
- (10) Any other factor(s) that may be relevant in determining the amount of a penalty: Considered, but not utilized for this calculation.

MAJOR	X MODERAT	E	MINOR
Penalty Matrix where the applicable statute provides	TVDE I	TVPE II	TVDE III

I	rix where the statute provides enalty up to	TYPE I	TYPE II	TYPE III
DEVIATION	MAJOR	\$12,500 to \$25,000	\$6,250 to \$12,500	\$2,500 to \$6,250
FROM	MODERATE	\$6,250 to \$12,500 \$12,500	\$2,500 to \$6,250	\$1,250 to \$2,500
STANDARD F	MINOR	\$2,500 to \$6,250	\$1,250 to \$2,500	\$250 to \$1,250

PENALTY MATRIX WORKSHEET

CITATION: Satellite containers closed

VIOLATION NO.: D (1)(b)

ТҮРЕ				
X TYPE I DIRECTLY related to protecting health, safety, welfare, or environment.	TYPE II INDIRECTLY related to protecting health, safety, welfare, or environment.	TYPE III INCIDENTAL to protecting health, safety, welfare, or environment.		

DEVIATION FROM THE STANDARD

THE DEGREE TO WHICH A PARTICULAR VIOLATION IS OUT OF COMPLIANCE WITH THE REQUIREMENT VIOLATED.

FACTORS CONSIDERED:

Taken from Part 1.10(A)(1)(b) of the Penalty Regulations.

- (1) The extent to which the act or failure to act was out of compliance: Respondent failed to close satellite containers holding hazardous waste. The requirement to close containers holding hazardous waste is an integral part of the regulatory program because this requirement reduces the potential for a spill or release.
- (2) **Environmental conditions**: Considered, but not utilized for this calculation.
- (3) Amount of the pollutant: Five 5-gallon containers were not closed in accordance with the HW Rules.
- (4) **Toxicity or nature of the pollutant:** All of the containers held spent Acetone and/or IPA. Acetone is a highly flammable liquid that has a flashpoint of 0°F, and IPA has a flashpoint of 53°F.
- (5) **Duration of the violation**: Unknown.
- (6) Areal extent of the violation: Considered, but not utilized for this calculation.

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- (7) Whether the person took reasonable and appropriate steps to prevent and/or mitigate the noncompliance: Respondent failed to take reasonable and appropriate steps to prevent the noncompliance by keeping the containers closed. The noncompliance was previously documented in an inspection by RIDEM on 13 February 2020 and Respondent was advised of the noncompliance at the time of the inspection. RIDEM has no information of what steps, if any, Respondent has taken to mitigate the noncompliance.
- (8) Whether the person has previously failed to comply with any regulations, order, statute, license, permit, or approval issued or adopted by the Department, or any law which the Department has the authority or responsibility to enforce: Considered, but not utilized for this calculation.
- (9) The degree of willfulness or negligence, including but not limited to, how much control the violator had over the occurrence of the violation and whether the violation was foreseeable: Respondent had complete control over the occurrence of the violation and failed to take steps to prevent the occurrence.
- (10) Any other factor(s) that may be relevant in determining the amount of a penalty: Considered, but not utilized for this calculation.

MAJOR	MODERATE		X MINOR
Penalty Matrix where the			
applicable statute provides	TYPE I	TYPE II	TYPE III

1	trix where the statute provides enalty up to	TYPE I	TYPE II	TYPE III
DEVIATION	MAJOR	\$12,500 to \$25,000	\$6,250 to \$12,500	\$2,500 to \$6,250
FROM	MODERATE	\$6,250 to \$12,500	\$2,500 to \$6,250	\$1,250 to \$2,500
STANDARD	MINOR	\$2,500 to \$6,250 \$6,250	\$1,250 to \$2,500	\$250 to \$1,250

PENALTY MATRIX WORKSHEET

CITATION: Accumulation date and secondary containment

VIOLATION NOs.: D (1)(c) and (d)

ТҮРЕ				
X TYPE I DIRECTLY related to protecting health, safety, welfare, or environment.	TYPE II INDIRECTLY related to protecting health, safety, welfare, or environment.	TYPE III INCIDENTAL to protecting health, safety, welfare, or environment.		

DEVIATION FROM THE STANDARD

THE DEGREE TO WHICH A PARTICULAR VIOLATION IS OUT OF COMPLIANCE WITH THE REQUIREMENT VIOLATED.

FACTORS CONSIDERED:

Taken from Part 1.10(A)(1)(b) of the Penalty Regulations.

- (1) The extent to which the act or failure to act was out of compliance: Respondent failed to mark accumulation containers with the date upon which the waste first began to accumulate. The accumulation start date enables generators and regulatory authorities to track the amount of time hazardous waste is stored at a facility. This requirement is of significant concern to the regulatory program because it helps ensure that hazardous waste is not stored onsite for extended periods of time. Storage exceeding certain time thresholds require the generator to obtain a hazardous waste storage permit. Respondent also failed to provide secondary containment for containers hold hazardous waste in storage. The containment system provides for the prevention of spills and leaks into areas where there may be personnel contact.
- (2) Environmental conditions: Considered, but not utilized for this calculation.
- (3) **Amount of the pollutant**: Four 55-gallon containers were not provided secondary containment and two 55-gallon containers were not marked with accumulation dates.
- (4) **Toxicity or nature of the pollutant**: All of the containers held spent Acetone/IPA mixtures. Acetone is a highly flammable liquid that has a flashpoint of 0°F, and IPA has a flashpoint of 53°F.
- (5) **Duration of the violation**: Unknown.
- (6) Areal extent of the violation: Considered, but not utilized for this calculation.

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- (7) Whether the person took reasonable and appropriate steps to prevent and/or mitigate the noncompliance: Respondent failed to take reasonable and appropriate steps to prevent the noncompliance by dating the containers and providing proper containment. RIDEM has no information of what steps, if any, Respondent has taken to mitigate the noncompliance.
- (8) Whether the person has previously failed to comply with any regulations, order, statute, license, permit, or approval issued or adopted by the Department, or any law which the Department has the authority or responsibility to enforce: Considered, but not utilized for this calculation.
- (9) The degree of willfulness or negligence, including but not limited to, how much control the violator had over the occurrence of the violation and whether the violation was foreseeable: Respondent had complete control over the occurrence of the violation and failed to take steps to prevent the occurrence.
- Any other factor(s) that may be relevant in determining the amount of a penalty: Considered, but not utilized for this calculation.

MAJOR		MODERATE		<u>X</u> MINOR	
Penalty Matrix where the applicable statute provides for a civil penalty up to \$25,000		TYPE I	TYPE II		TYPE III
	MAJOR	\$12,500 to \$25,000	\$6,250 to	\$12,500	\$2,500 to \$6,250
DEVIATION FROM	MODERATE	\$6,250 to \$12,500	\$2,500 to \$6,250		\$1,250 to \$2,500
STANDARD	MINOR	\$2,500 to \$6,250 \$2,500 (Date) \$2,500 (Cntmnt)	\$1,250 to	\$2,500	\$250 to \$1,250