

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.) Civil Case No. 3:25-cv-01319-ADC
) Hon. Aida M. Delgado-Colon
)
STERI-TECH, INC.,)
)
Defendant.)

CONSENT DECREE

TABLE OF CONTENTS

I.	JURISDICTION AND VENUE	2
II.	APPLICABILITY	2
III.	DEFINITIONS.....	3
IV.	CIVIL PENALTY.....	5
V.	PERFORMANCE OF CONSENT DECREE OBLIGATIONS	6
VI.	COMPLIANCE REQUIREMENTS.....	7
VII.	ADDITIONAL INJUNCTIVE RELIEF	9
VIII.	REPORTING REQUIREMENTS	10
IX.	STIPULATED PENALTIES	12
X.	FORCE MAJEURE	16
XI.	DISPUTE RESOLUTION	18
XII.	INFORMATION COLLECTION AND RETENTION	21
XIII.	EFFECT OF SETTLEMENT/RESERVATION OF RIGHTS	23
XIV.	COSTS	24
XV.	NOTICES.....	24
XVI.	EFFECTIVE DATE.....	25
XVII.	RETENTION OF JURISDICTION	26
XVIII.	MODIFICATION	26
XIX.	TERMINATION.....	26
XX.	PUBLIC PARTICIPATION	28
XXI.	SIGNATORIES/SERVICE.....	28
XXII.	INTEGRATION	29
XXIII.	26 U.S.C. SECTION 162(F)(2)(A)(II) IDENTIFICATION.....	29
XXIV.	HEADINGS	29
XXV.	FINAL JUDGMENT	29

Plaintiff United States of America, on behalf of the United States Environmental Protection Agency (EPA), has filed a complaint in this action alleging that Defendant Steri-Tech, Inc. (“Defendant” or “Steri-Tech”) is liable under Clean Air Act (CAA) Section 113(b), 42 U.S.C. § 7413(b), for violating 40 C.F.R. Part 63, Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities (“NESHAP Subpart O” or “Subpart O”) and the Commonwealth of Puerto Rico’s Regulations for the Control of Atmospheric Pollution (RCAP) Rules 203 and 204(A)(3), incorporated into the EPA-approved State Implementation Plan (SIP) for Puerto Rico, at Defendant’s ethylene oxide (“EtO”) sterilization facility located at State Road 701 Km. 0.7 Salinas Industrial Park, in Salinas, Puerto Rico (the “Facility”).

Defendant does not admit, and specifically denies, any liability to the United States arising out of the transactions or occurrences alleged in the Complaint. This Consent Decree constitutes a negotiated resolution of the liability alleged in the Complaint, and shall not be construed as an admission, adjudication, or measure of the nature, extent, or magnitude of any actual or potential injury, damage, or harm to any person, property, or the environment by Defendant.

The Parties recognize, and the Court by entering this Consent Decree finds, that this Consent Decree has been negotiated by the Parties in good faith and will avoid further litigation between the Parties and that this Consent Decree is fair, reasonable, and in the public interest.

NOW, THEREFORE, before the taking of any testimony, without the adjudication or admission of any issue of fact or law except as provided in Section I (Jurisdiction and Venue), and with the consent of the Parties, IT IS HEREBY ADJUDGED, ORDERED, AND DECREED as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of this action, pursuant to 28 U.S.C. §§ 1331, 1345, and 1355, and CAA Section 113(b), 42 U.S.C. § 7413(b), and over the Parties. Venue lies in this District pursuant to CAA Section 113(b), 42 U.S.C. § 7413(b), and 28 U.S.C. §§ 1391(b) and 1395(a), because the violations alleged in the Complaint are alleged to have occurred in, and Defendant conducts business in, this judicial district. For purposes of this Decree, or any action to enforce this Decree, Defendant consents to the Court's jurisdiction over this Decree and any such action and over Defendant and consents to venue in this judicial district.

2. For purposes of this Consent Decree only, Defendant agrees that the Complaint states claims upon which relief may be granted pursuant to CAA Section 113(b), 42 U.S.C. 7413(b).

II. APPLICABILITY

3. The obligations of this Consent Decree apply to and are binding upon the United States and upon Defendant and any successors, assigns, or other entities or persons otherwise bound by law.

4. No transfer of ownership or operation of the Facility, whether in compliance with the procedures of this Paragraph or otherwise, shall relieve Defendant of its obligation to ensure that the terms of the Decree are implemented. At least 30 Days prior to such transfer, Defendant shall provide a copy of this Consent Decree to the proposed transferee and shall simultaneously provide written notice of the prospective transfer, together with a copy of the proposed written agreement, to EPA, the United States Department of Justice (DOJ), the Office of the United States Attorney for the District of Puerto Rico, and the Commonwealth of Puerto Rico

Department of Natural and Environmental Resources (DNER) in accordance with Section XV (Notices). Any attempt to transfer ownership or operation of the Facility without complying with this Paragraph constitutes a violation of this Decree.

5. Defendant shall provide a copy of this Consent Decree to all officers, employees, and agents whose duties might reasonably include compliance with any provision of this Decree, as well as to any contractor retained to perform work required under this Consent Decree. Defendant shall condition any such contract upon performance of the work in conformity with the terms of this Consent Decree.

6. In any action to enforce this Consent Decree, Defendant shall not raise as a defense the failure by any of its officers, directors, employees, agents, or contractors to take any actions necessary to comply with the provisions of this Consent Decree.

III. DEFINITIONS

7. Terms used in this Consent decree that are defined in the CAA or in the applicable regulations promulgated pursuant to the CAA have the meanings assigned to them in the CAA or such regulations, unless otherwise provided in this Decree. Whenever the terms set forth below are used in this Consent Decree, the following definitions apply:

“Complaint” means the complaint filed by the United States in this action;

“Consent Decree” or “Decree” means this Decree;

“Date of Lodging” means the date this Consent Decree is filed for lodging with the Clerk of the Court for the United States District Court for the District of Puerto Rico;

“Day” means a calendar day unless expressly stated to be a business day. In computing any period of time for a deadline under this Consent Decree, where the last day would fall on a

Saturday, Sunday, or federal holiday, the period runs until the close of business of the next business day;

“Defendant” means Steri-Tech, Inc.;

“DOJ” means the United States Department of Justice and any of its successor departments or agencies;

“DNER” means the Puerto Rico Department of Natural and Environmental Resources and any of its successor departments or agencies;

“EPA” means the United States Environmental Protection Agency and any of its successor departments or agencies;

“Effective Date” means the definition provided in Section XVI;

“Facility” means Defendant’s ethylene oxide sterilization facility located at State Road 701 Km. 0.7 Salinas Industrial Park, Salinas, Puerto Rico;

“National Emission Standards for Hazardous Air Pollutants” or “NESHAP” means emissions standards promulgated pursuant to CAA Section 112, 42 U.S.C. § 7412;

“NESHAP Subpart O” or “Subpart O” means the Ethylene Oxide Emissions Standards for Sterilization Facilities, codified at 40 C.F.R. Part 63, Subpart O;

“Paragraph” means a portion of this Decree identified by an Arabic numeral;

“Parties” means the United States and Defendant;

“RCAP” means the Puerto Rico Regulations for the Control of Atmospheric Pollution, as submitted to EPA on September 29, 1995, as part of the State Implementation Plan for the Commonwealth of Puerto Rico, which EPA approved on January 22, 1997. 62 Fed. Reg. 3211;

“Section” means a portion of this Decree identified by a Roman numeral;

“SIP” means a federally approved State Implementation Plan;

“State” means the Commonwealth of Puerto Rico; and

“United States” means the United States of America, acting on behalf of EPA.

IV. CIVIL PENALTY

8. Defendant shall pay the sum of \$700,000 as a civil penalty as follows: (a) within 30 Days after the Effective Date, Defendant shall pay the sum of \$350,000, together with interest accruing from the Date of Lodging of the Consent Decree, at the rate specified in 28 U.S.C. § 1961 as of the Date of Lodging; and (b) within one year after the Effective Date, Defendant shall pay the sum of \$350,000, together with interest accruing from the Date of Lodging of the Consent Decree, at the rate specified in 28 U.S.C. § 1961 as of the Date of Lodging

9. Defendant shall pay the civil penalty due, together with interest, by FedWire Electronic Funds Transfer (EFT) to the DOJ account, in accordance with instructions provided to Defendant by the Financial Litigation Unit (FLU) of the United States Attorney’s Office for the District of Puerto Rico after the Effective Date. The payment instructions provided by the FLU will include a Consolidated Debt Collection System (CDCS) number, which Defendant shall use to identify all payments required to be made in accordance with this Consent Decree. The FLU will provide the payment instructions to:

Andrés Vivoni
Vice President and General Manager
Steri-Tech, Inc.
P.O. Box 1145, Salinas, PR 00751
Tel (787) 824-4040
avivoni@steri-tech.com

on behalf of Defendant. Defendant may change the individual to receive payment instructions on its behalf by providing written notice of such change to DOJ and EPA in accordance with Section XV (Notices).

10. At the time of payment, Defendant shall send notice that payment has been made: (i) to EPA via email at cinwd_acctsreceivable@epa.gov or via regular mail at EPA Cincinnati Finance Office, 26 W. Martin Luther King Drive, Cincinnati, Ohio 45268; (ii) to DOJ via email or regular mail in accordance with Section XV; and (iii) to EPA in accordance with Section XV. Such notice shall state that the payment is for the civil penalty owed pursuant to the Consent Decree in *United States v. Steri-Tech, Inc.* and shall reference the civil action number, CDCS Number, and DOJ case number 90-5-2-1-12790.

11. Defendant shall not deduct any penalties paid under this Decree pursuant to this Section or Section IX (Stipulated Penalties) in calculating its federal income tax.

V. PERFORMANCE OF CONSENT DECREE OBLIGATIONS

12. Approval of Deliverables. After review of any plan, report, or other item that is required to be submitted for approval pursuant to this Consent Decree, EPA will in writing: (a) approve the submission; (b) approve the submission upon specified conditions; (c) approve part of the submission and disapprove the remainder; or (d) disapprove the submission.

13. If the submission is approved pursuant to Paragraph 12(a), Defendant shall take all actions required by the plan, report, or other document, in accordance with the schedules and requirements of the plan, report, or other document, as approved. If the submission is conditionally approved or approved only in part pursuant to Paragraph 12(b) or (c), Defendant shall, upon written direction from EPA, take all actions required by the approved plan, report, or other item that EPA determines are technically severable from any disapproved portions.

14. If the submission is disapproved in whole or in part pursuant to Paragraph 12(c) or (d), Defendant shall, within 45 Days or such other time as the Parties agree to in writing, correct all deficiencies and resubmit the plan, report, or other item, or disapproved portion

thereof, for approval, in accordance with the preceding Paragraphs. If the resubmission is approved in whole or in part, Defendant shall proceed in accordance with the preceding Paragraph.

15. If a resubmitted plan, report, or other item, or portion thereof, is disapproved in whole or in part, EPA may again require Defendant to correct any deficiencies, in accordance with the preceding Paragraphs, or may itself correct any deficiencies.

16. If Defendant elects to invoke Dispute Resolution as set forth in Section XI (Dispute Resolution) concerning a decision by EPA to disapprove, approve on specified conditions, or modify a deliverable, Defendant shall do so by sending a Notice of Dispute in accordance with Paragraph 54 within 30 Days (or such other time as the Parties agree to in writing) after receipt of the applicable decision.

17. Any stipulated penalties applicable to the original submission, as provided in Section IX, accrue during the 45 Day period or other specified period, but shall not be payable unless the resubmission is untimely or is disapproved in whole or in part; provided that, if the original submission was so deficient as to constitute a material breach of Defendant's obligations under this Decree, the stipulated penalties applicable to the original submission shall be due and payable notwithstanding any subsequent resubmission.

VI. COMPLIANCE REQUIREMENTS

18. NESHAP Subpart O. As of the Date of Lodging of this Consent Decree, the applicable NESHAP Subpart O emission standards require Defendant to continuously reduce EtO emissions by at least 99% for each sterilization chamber vent ("SCV") and to continuously reduce EtO emissions by at least 99% or a maximum outlet concentration of 1 ppmv, whichever is less stringent, for each aeration room vent ("ARV"). To assure compliance with these

standards, Defendant shall operate its currently permitted Thermal Oxidizer (TO) and/or Catalytic Recuperative Oxidizer (CRO) control device(s) in accordance with (i) NESHAP Subpart O and (ii) compliance parameters in Paragraphs 19 and 20 of this Consent Decree, as applicable.

19. The TO shall be operated in accordance with NESHAP Subpart O, including any amendments thereto, and the operational parameters, limits, and monitoring methods set forth in the December 2, 2025 “Notification of Compliance Status (NOCS) Report – 40 C.F.R. 63.9(h)(2)” for the TO, reflecting the September 2025 TO performance test (collectively, the “TO Compliance Parameters”). The TO Compliance Parameters include the minimum TO temperature controller setpoint of 1550°F and continuous monitoring and recording of the TO temperature parameter using a data acquisition system. The TO Compliance Parameters shall apply at all times that the TO is in operation to oxidize EtO.

20. The CRO shall be operated in accordance with NESHAP Subpart O, including any amendments thereto, and the operational parameters, limits, monitoring methods, and work practices set forth in the May 12, 2025 “Notification of Compliance Status (NOCS) Report – 40 C.F.R. 63.9(h)(2)” for the CRO and the “Clarification to the NOCS Report Requested by EPA” submitted by Defendant on August 29, 2025, reflecting the September 2024 CRO performance test (collectively, the “CRO Compliance Parameters”). The CRO Compliance Parameters include the minimum temperature controller setpoint of 860°F and continuous monitoring and recording of the CRO temperature parameter using a data acquisition system. The CRO Compliance Parameters shall apply at all times that the CRO is in operation to oxidize EtO.

21. In addition to the TO and CRO, Defendant may use an alternative emissions control device, where Defendant has: (i) conducted a performance test for such control device

pursuant to an EPA-approved test protocol; (ii) submitted an EPA-approved NOCS establishing compliance parameters sufficient to ensure continuous compliance with NESHAP Subpart O and the Additional Injunctive Relief standard of Paragraph 24 if Defendant seeks to utilize the new control device for compliance with that provision; and (iii) obtained all required permits from DNER to authorize operation of the new emissions control device.

22. Compliance parameters may be modified, subject to EPA approval, if a new compliance demonstration / performance test is conducted which reestablishes any operational parameter in continuous compliance with the EtO emissions standards set forth in Paragraphs 18 and 23 of this Consent Decree.

23. If any revision to NESHAP Subpart O imposes stricter requirements during the pendency of this Consent Decree, Defendant shall comply with any such stricter requirements in lieu of the requirement set forth in Paragraph 18.

VII. ADDITIONAL INJUNCTIVE RELIEF

24. Emissions Reduction. As of the Date of Lodging of this Consent Decree, Defendant shall continuously reduce EtO emissions at the Facility by at least 99.99% for each SCV. Defendant shall demonstrate compliance with this standard through compliance with the TO Compliance Parameters in effect as of the Date of Lodging. Defendant may identify up to 14 Days annually, commencing on the Date of Lodging, as an “Excluded Maintenance Day” when Defendant is not obligated to comply with the 99.99% emissions reduction requirement set forth in this Paragraph. Excluded Maintenance Days are intended to coincide with the performance of maintenance on the TO. Defendant must provide advance notice to EPA of its designation of any Day as an Excluded Maintenance Day, and such designation cannot be retroactively applied.

25. Defendant shall submit the data establishing compliance with its Additional Injunctive Relief obligation (TO hourly and daily average temperature data in Excel format) to EPA in accordance with Section XV (Notices) on a quarterly basis. Defendant shall also post the TO daily average temperature data at the top banner of its public website under a tab labeled “EtO Additional Injunctive Relief Compliance Data” on the same quarterly schedule.

VIII. REPORTING REQUIREMENTS

26. Defendant shall submit the following reports to EPA and DOJ at the addresses set forth Section XV (Notices):

a. By January 31st, April 30th, July 31st, and October 31st of each year after the lodging of this Consent Decree, until termination of this Decree pursuant to Section XIX (Termination), Defendant shall submit electronically a quarterly report for the preceding three months that includes the status of any compliance measures; problems encountered or anticipated, together with implemented or proposed solutions; operation and maintenance; and reports to state agencies.

b. The report shall also include a description of any non-compliance with the requirements of this Consent Decree and an explanation of the likely cause of the non-compliance and of the remedial steps taken, or to be taken, to prevent or minimize such non-compliance. If Defendant fails to comply with, or has reason to believe that it may fail to comply with, any requirement of this Consent Decree, Defendant shall notify DOJ and EPA of such non-compliance and its likely duration, in writing, within 10 business days of the Day Defendant first becomes aware of the non-compliance, with an explanation of the likely cause of the non-compliance and of the remedial steps taken, or to be taken, to prevent or minimize such non-compliance. If the cause of the non-

compliance cannot be fully explained at the time the report is due, Defendant shall so state in the report. Defendant shall investigate the cause of the non-compliance and shall then submit an amendment to the report, including a full explanation of the cause of the non-compliance, within 30 Days of the Day Defendant becomes aware of the cause of the non-compliance. Nothing in this Paragraph or the following Paragraph relieves Defendant of its obligation to provide the notice required by Section X (Force Majeure).

c. By January 31st, April 30th, July 31st, and October 31st of each year after the lodging of this Consent Decree, until termination of this Consent Decree pursuant to Section XIX (Termination), Defendant shall submit electronically a quarterly report for the preceding three months that includes a complete set of operational and monitoring data in Excel format for any pollution control device in use during such quarter, including all compliance parameters relating to the TO, CRO, or other subsequently authorized emissions control device.

27. Whenever any non-compliance with this Consent Decree or of any applicable permits or any other event affecting Defendant's performance under this Decree may pose an immediate threat to the public health or welfare or the environment, Defendant shall notify both Robert Buettner by telephone at (212) 637-5031 or by email to Buettner.Robert@epa.gov and Nancy Rodriguez by telephone at (787) 977-5887 or by email at Rodriguez.Nancy@epa.gov as soon as possible, but no later than 24 hours after Defendant first knew of the non-compliance or event. This procedure is in addition to the requirements set forth in the preceding Paragraph.

28. Each report submitted by Defendant under this Section shall be signed by an official of the submitting party and include the following certification:

I certify under penalty of perjury that this document and all attachments were prepared under my direction or supervision in

accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I have no personal knowledge that the information submitted is other than true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

29. This certification requirement does not apply to emergency or similar notifications where compliance would be impractical.

30. The reporting requirements of this Consent Decree do not relieve Defendant of any reporting obligations required by the CAA or implementing regulations, or by any other federal, state, or local law, regulation, permit, or other requirement.

31. Any information provided pursuant to this Consent Decree may be used by the United States in any proceeding to enforce the provisions of this Consent Decree and as otherwise permitted by law.

IX. STIPULATED PENALTIES

32. Defendant shall be liable for stipulated penalties to the United States for violations of this Consent Decree as specified below, unless excused under Section X (Force Majeure). A violation includes failing to perform any obligation required by the terms of this Decree, including any work plan or schedule approved under this Decree, according to all applicable requirements of this Decree and within the specified time schedules established by or approved under this Decree.

33. Late Payment of Civil Penalty. If Defendant fails to pay the civil penalty required to be paid under Section IV (Civil Penalty) when due, Defendant shall pay a stipulated penalty of \$5,000 per Day for each Day that the payment is late.

34. Compliance and Additional Injunctive Relief Milestones.

a. The following stipulated penalties shall accrue per violation per Day for each violation of the requirements identified in subparagraph 34.b.:

<u>Penalty Per Violation Per Day</u>	<u>Period of Noncompliance</u>
\$1,500	1st through 14th Day
\$3,000	15th through 30th Day
\$5,000	31st Day and beyond

b. Requirements subject to stipulated penalties in Subparagraph a:

- (1) Emissions limits – regulatory compliance (Paragraph 18);
- (2) Compliance parameters (Paragraphs 19-20); and
- (3) Emissions limits – Additional Injunctive Relief (Paragraph 24).

35. Reporting and Recordkeeping Requirements. The following stipulated penalties shall accrue per violation per Day for each violation of the reporting and recordkeeping requirements of Paragraph 25 and Section VIII:

<u>Penalty Per Violation Per Day</u>	<u>Period of Noncompliance</u>
\$500.....	1st through 14th Day
\$750.....	15th through 30th Day
\$1,250	31st Day and beyond

36. Transfer of Ownership. If Defendant fails to provide written notice to the United States at least 30 Days prior to any transfer of any portion of the Facility or provide a copy of the proposed written agreement with the transferee as required by Paragraph 4, Defendant shall pay a stipulated penalty of \$10,000 per occurrence.

37. Other Violations. The following stipulated penalties shall accrue per violation per Day for each violation of any other requirement of this Consent Decree:

<u>Penalty Per Violation Per Day</u>	<u>Period of Noncompliance</u>
\$500.....	1st through 14th Day
\$1,000	15th Day and beyond

38. Stipulated penalties under this Section shall begin to accrue on the Day after performance is due or on the Day a violation occurs, whichever is applicable, and shall continue to accrue until performance is satisfactorily completed or until the violation ceases. Stipulated penalties shall accrue simultaneously for separate violations of this Consent Decree.

39. Defendant shall pay any stipulated penalty within 30 Days of receiving the United States' written demand.

40. The United States may in the unreviewable exercise of its discretion, reduce or waive stipulated penalties otherwise due it under this Consent Decree.

41. Stipulated penalties shall continue to accrue as provided in Paragraph 38, during any Dispute Resolution, but need not be paid until the following:

a. If the dispute is resolved by agreement of the Parties or by a decision of EPA that is not appealed to the Court, Defendant shall pay accrued penalties determined to be owing, together with interest, to the United States within 30 Days of the effective date of the agreement or the receipt of EPA's decision or order.

b. If the dispute is appealed to the Court and the United States prevails in whole or in part, Defendant shall pay all accrued penalties determined by the Court to be owing, together with interest, within 60 Days of receiving the Court's decision or order, except as provided in subparagraph c, below.

c. If any Party appeals the District Court's decision, Defendant shall pay all accrued penalties determined to be owing, together with interest, within 15 Days of receiving the final appellate court decision.

42. Obligations Prior to the Effective Date. Upon the Effective Date, the stipulated penalty provisions of this Decree shall be retroactively enforceable with regard to any and all violations of Paragraphs 18-25 that have occurred prior to the Effective Date, provided that stipulated penalties that may have accrued prior to the Effective Date may not be collected unless and until this Consent Decree is entered by the Court.

43. Defendant shall pay stipulated penalties owing to the United States in the manner set forth in Paragraph 9 and with the confirmation notices required by Paragraph 10, except that the transmittal letter shall state that the payment is for stipulated penalties and shall state for which violation(s) the penalties are being paid.

44. If Defendant fails to pay stipulated penalties according to the terms of this Consent Decree, Defendant shall be liable for interest on such penalties, as provided for in 28 U.S.C. § 1961, accruing as of the date payment became due. Nothing in this Paragraph shall be construed to limit the United States from seeking any remedy otherwise provided by law for Defendant's failure to pay any stipulated penalties.

45. The payment of penalties and interest, if any, shall not alter in any way Defendant's obligation to complete the performance of the requirements of this Consent Decree.

46. Non-Exclusivity of Remedy. Stipulated penalties are not the United States' exclusive remedy for violations of this Consent Decree. Subject to the provisions of Section XIII (Effect of Settlement/Reservation of Rights), the United States expressly reserves the right to seek any other relief it deems appropriate for Defendant's violation of this Decree or applicable

law, including but not limited to an action against Defendant for statutory penalties, additional injunctive relief, mitigation or offset measures, and/or contempt. However, the amount of any statutory penalty assessed for a violation of this Consent Decree shall be reduced by an amount equal to the amount of any stipulated penalty assessed and paid pursuant to this Consent Decree.

X. FORCE MAJEURE

47. “Force majeure,” for purposes of this Consent Decree, means any event arising from causes beyond the control of Defendant, of any entity controlled by Defendant, or of Defendant’s contractors, that delays or prevents the performance of any obligation under this Consent Decree despite Defendant’s best efforts to fulfill the obligation. Given the need to protect public health and welfare and the environment, the requirement that Defendant exercise “best efforts to fulfill the obligation” includes using best efforts to anticipate any potential force majeure and best efforts to address the effects of any potential force majeure (a) as it is occurring and (b) following the potential force majeure, such that any delay or non-performance is, and any adverse effects of the delay or non-performance are, minimized to the greatest extent possible. “Force majeure” does not include financial inability to perform any obligation under this Consent Decree.

48. If any event occurs for which Defendant will or may claim a force majeure, Defendant shall provide notice by email to EPA. The deadline for the initial notice is three Days after Defendant first knew or should have known that the event would likely delay or prevent performance. Defendant shall be deemed to know of any circumstance of which any contractor of, subcontractor of, or entity controlled by Defendant knew or should have known.

49. Regardless of whether Defendant seeks to assert a claim of force majeure concerning the event, within seven Days after the notice under Paragraph 48, Defendant shall

submit a further notice to EPA that includes (a) an explanation and description of the event and its effect on Defendant's completion of the requirements of the Consent Decree; (b) a description and schedule of all actions taken or to be taken to prevent or minimize the delay and/or other adverse effects of the event; (c) if applicable, the proposed extension of time for Defendant to complete the requirements of the Consent Decree; (d) Defendant's rationale for attributing such delay to a force majeure if it intends to assert such a claim; (e) a statement as to whether, in the opinion of Defendant, such event may cause or contribute to an endangerment to public health or welfare or the environment; and (f) all available proof supporting any claim that the delay was attributable to a force majeure.

50. Failure to submit a timely or complete notice or claim under Paragraph 48 or 49 regarding an event precludes Defendant from asserting any claim of force majeure regarding that event, provided, however, that EPA may, in its unreviewable discretion, excuse such failure if it is able to assess to its satisfaction whether the event is a force majeure, and whether Defendant has exercised its best efforts, under Paragraph 47.

51. After receipt of any claim of force majeure, EPA will notify Defendant of its determination whether Defendant is entitled to relief under Paragraph 47, and, if so, the excuse of, or the extension of time for, performance of the obligations affected by the force majeure. An excuse of, or extension of the time for performance of, the obligations affected by the force majeure does not, of itself, excuse or extend the time for performance of any other obligation.

52. If Defendant elects to invoke the dispute resolution procedures set forth in Section XI (Dispute Resolution), it shall do so no later than 15 Days after receipt of EPA's notice. In any such proceeding, Defendant has the burden of proving that it is entitled to relief under Paragraph 47, that its proposed excuse or extension was or will be warranted under the

circumstances, and that it complied with the requirements of Paragraphs 47-49. If Defendant carries this burden, the delay or non-performance at issue shall be deemed not to be a violation by Defendant of the affected obligation of this Consent Decree identified to EPA and the Court.

XI. DISPUTE RESOLUTION

53. Unless otherwise expressly provided for in this Consent Decree, the dispute resolution procedures of this Section shall be the exclusive mechanism to resolve disputes arising under or with respect to this Consent Decree. Defendant's failure to seek resolution of a dispute under this Section concerning an issue of which it had notice and an opportunity to dispute under this Section prior to an action by the United States to enforce any obligation of Defendant arising under this Decree precludes Defendant from raising any such issue as a defense to any such enforcement action.

54. Informal Dispute Resolution. Any dispute subject to Dispute Resolution under this Consent Decree shall first be the subject of informal negotiations. The dispute shall be considered to have arisen when Defendant sends DOJ and EPA a written Notice of Dispute. Such Notice of Dispute shall state clearly the matter in dispute. The period of informal negotiations shall not exceed 30 Days from the date the dispute arises, unless that period is modified by written agreement. If the Parties cannot resolve a dispute by informal negotiations, then the position advanced by the United States shall be considered binding unless, within 30 Days after the conclusion of the informal negotiation period, Defendant invokes formal dispute resolution procedures as set forth below.

55. Formal Dispute Resolution. Defendant shall invoke formal dispute resolution procedures, within the time period provided in the preceding Paragraph, by sending DOJ and EPA a written Statement of Position regarding the matter in dispute. The Statement of Position

shall include, but need not be limited to, any factual data, analysis, or opinion supporting Defendant's position and any supporting documentation relied upon by Defendant.

56. The United States will send Defendant its Statement of Position within 60 Days of receipt of Defendant's Statement of Position. The United States' Statement of Position shall include, but need not be limited to, any factual data, analysis, or opinion supporting that position and any supporting documentation relied upon by the United States. The United States' Statement of Position is binding on Defendant, unless Defendant files a motion for judicial review of the dispute in accordance with the following Paragraph.

57. Judicial Dispute Resolution. Defendant may seek judicial review of the dispute by filing with the Court and serving on the United States a motion requesting judicial resolution of the dispute. The motion (a) must be filed within ten Days of receipt of the United States' Statement of Position pursuant to the preceding Paragraph; (b) may not raise any issue not raised in informal dispute resolution pursuant to Paragraph 54, unless the United States raises a new issue of law or fact in the Statement of Position; (c) shall contain a written statement of Defendant's position on the matter in dispute, including any supporting factual data, analysis, opinion, or documentation, and (d) shall set forth the relief requested and any schedule within which the dispute must be resolved for orderly implementation of the Consent Decree.

58. The United States shall respond to Defendant's motion within the time period allowed by the Local Rules of this Court. Defendant may file a reply memorandum, to the extent permitted by the Local Rules.

59. Standard of Review

a. Disputes Concerning Matters Accorded Record Review. Except as otherwise provided in this Consent Decree, in any dispute brought under Paragraph 55

pertaining to the adequacy or appropriateness of plans, procedures to implement plans, schedules or any other items requiring approval by EPA under this Consent Decree; the adequacy of the performance of work undertaken pursuant to this Consent Decree; and all other disputes that are accorded review on the administrative record under applicable principles of administrative law, Defendant shall have the burden of demonstrating, based on the administrative record, that the position of the United States is arbitrary and capricious or otherwise not in accordance with law.

b. Other Disputes. Except as otherwise provided in this Consent Decree, in any other dispute brought under Paragraph 55, Defendant shall bear the burden of demonstrating that its position complies with this Consent Decree and that its proposal will achieve compliance with the terms and conditions of this Consent Decree, its permits, and the CAA in an expeditious manner and that implementation of its proposal will result in equivalent or greater environmental protection that would implementation of United States' position.

60. The invocation of dispute resolution procedures under this Section shall not, by itself, extend, postpone, or affect in any way any obligation of Defendant under this Consent Decree, unless and until final resolution of the dispute so provides. Stipulated penalties with respect to the disputed matter shall continue to accrue from the first Day of noncompliance, but payment shall be stayed pending resolution of the dispute as provided in Paragraph 41. If Defendant does not prevail on the disputed issue, stipulated penalties shall be assessed and paid as provided in Section IX (Stipulated Penalties).

XII. INFORMATION COLLECTION AND RETENTION

61. The United States and its representatives, including attorneys, contractors, and consultants, shall have the right of entry into any facility covered by this Consent Decree, at all reasonable times, upon presentation of credentials, to:

- a. monitor the progress of activities required under this Consent Decree;
- b. verify any data or information submitted to the United States in accordance with the terms of this Consent Decree;
- c. obtain samples and, upon request, splits of any samples taken by Defendant or its representatives, contractors, or consultants;
- d. obtain documentary evidence, including photographs and similar data; and
- e. assess Defendant's compliance with this Consent Decree.

62. Upon request, Defendant shall provide EPA or its authorized representatives splits of any samples taken by Defendant. Upon request, EPA shall provide Defendant splits of any samples taken by EPA.

63. Until five years after the termination of this Consent Decree, Defendant shall retain, and shall instruct its contractors and agents to preserve, all non-identical copies of all documents, records, or other information (including documents, records, or other information in electronic form) in its or its contractors' or agents' possession or control, or that come into its or its contractors' or agents' possession or control, and that relate in any manner to Defendant's performance of its obligations under this Consent Decree. This information-retention requirement shall apply regardless of any contrary corporate or institutional policies or procedures. At any time during this information-retention period, upon request by the United

States, Defendant shall provide copies of any documents, records, or other information required to be maintained under this Paragraph.

64. At the conclusion of the information-retention period provided in the preceding Paragraph, Defendant shall notify the United States at least 90 Days prior to the destruction of any documents, records, or other information subject to the requirements of the preceding Paragraph and, upon request by the United States, Defendant shall deliver any such documents, records, or other information to EPA. Defendant may assert that certain documents, records, or other information is privileged under the attorney-client privilege, or any other privilege recognized by federal law. If Defendant asserts such a privilege, it shall provide the following: (a) the title of the document, record, or information; (b) the date of the document, record, or information; (c) the name and title of each author of the document, record, or information; (d) the name and title of each addressee and recipient; (e) a description of the subject of the document, record, or information; and (f) the privilege asserted by Defendant. However, no documents, records, or other information created or generated pursuant to the requirements of this Consent Decree shall be withheld on grounds of privilege.

65. Defendant may also assert that information required to be provided under this Section is protected as Confidential Business Information (CBI) under 40 C.F.R. Part 2. As to any information that Defendant seeks to protect as CBI, Defendant shall follow the procedures set forth in 40 C.F.R. Part 2.

66. This Consent Decree in no way limits or affects any right of entry and inspection, or any right to obtain information, held by the United States or the State pursuant to applicable federal or state laws, regulations, or permits, nor does it limit or affect any duty or obligation of

Defendant to maintain documents, records, or other information imposed by applicable federal or state laws, regulations, or permits.

XIII. EFFECT OF SETTLEMENT/RESERVATION OF RIGHTS

67. This Consent Decree resolves only the civil claims of the United States for the violations alleged in the Complaint filed in this action through the Date of Lodging.

68. The United States reserves all legal and equitable remedies available to enforce the provisions of this Consent Decree. This Consent Decree shall not be construed to limit the rights of the United States to obtain penalties or injunctive relief under the CAA or implementing regulations, or under other federal laws, regulations, or permit conditions, except as expressly specified in Paragraph 67. The United States further reserves all legal and equitable remedies to address any conditions if there is or may be an imminent and substantial endangerment to the public health or welfare or the environment arising at, or posed by, Defendant's Facility, whether related to the violations addressed in this Consent Decree or otherwise.

69. In any subsequent administrative or judicial proceeding initiated by the United States for injunctive relief, civil penalties, other appropriate relief relating to the Facility or Defendant's violations, Defendant shall not assert, and may not maintain, any defense or claim based upon the principles of waiver, claim preclusion (*res judicata*), issue preclusion (*collateral estoppel*), claim-splitting, or other defenses based upon any contention that the claims raised by the United States in the subsequent proceeding were or should have been brought in the instant case, except with respect to claims that have been specifically resolved pursuant to Paragraph 67.

70. This Consent Decree is not a permit, or a modification of any permit, under any federal, State, or local laws or regulations. Defendant is responsible for achieving and maintaining complete compliance with all applicable federal, State, and local laws, regulations,

and permits; and Defendant's compliance with this Consent Decree shall be no defense to any action commenced pursuant to any such laws, regulations, or permits, except as set forth herein. The United States does not, by its consent to the entry of this Consent Decree, warrant or aver in any manner that Defendant's compliance with any aspect of this Consent Decree will result in compliance with provisions of the CAA, 42 U.S.C. § 7401, et seq., or with any other provisions of federal, State, or local laws, regulations, or permits.

71. This Consent Decree does not limit or affect the rights of Defendant or of the United States against any third parties, not party to this Consent Decree, nor does it limit the rights of third parties, not party to this Consent Decree, against Defendant, except as otherwise provided by law.

72. This Consent Decree shall not be construed to create rights in, or grant any cause of action to, any third party not party to this Consent Decree.

XIV. COSTS

73. The Parties shall bear their own costs of this action, including attorneys' fees, except that the United States shall be entitled to collect the costs (including attorneys' fees) incurred in any action necessary to collect any portion of the civil penalty or any stipulated penalties due but not paid by Defendant.

XV. NOTICES

74. Unless otherwise specified in this Decree, whenever notifications, submissions, or communications are required by this Consent Decree, they shall be made in writing and sent by mail or email (with a preference for email), addressed as follows:

As to DOJ by email (preferred): eescdcopy.enrd@usdoj.gov
Re: DJ # 90-5-2-1-12790

As to DOJ by mail: EES Case Management Unit
Environment and Natural Resources Division
U.S. Department of Justice
P.O. Box 7611
Washington, DC 20044-7611
Re: DJ # 90-5-2-1-12790

As to EPA by email: villatora.liliana@epa.gov
buettner.robert@epa.gov
patel.harish@epa.gov
rivera.alex@epa.gov
patel.hannah@epa.gov

As to Defendant: Jorge Andrés Vivoni
P.O. Box 1145
Salinas, PR 00751
avivoni@steri-tech.com

75. Any Party may, by written notice to the other Parties, change its designated notice recipient or notice address provided above.

76. Notices submitted pursuant to this Section shall be deemed submitted upon mailing or transmission by email, unless otherwise provided in this Consent Decree or by mutual agreement of the Parties in writing.

XVI. EFFECTIVE DATE

77. The Effective Date of this Consent Decree shall be the date upon which this Consent Decree is entered by the Court or a motion to enter the Consent Decree is granted, whichever occurs first, as recorded on the Court's docket; provided, however, that Defendant hereby agrees that it shall be bound to perform duties scheduled to occur prior to the Effective Date. In the event the United States withdraws or withholds consent to this Consent Decree before entry, or the Court declines to enter the Consent Decree, then the preceding requirement to perform duties scheduled to occur before the Effective Date shall terminate.

XVII. RETENTION OF JURISDICTION

78. The Court shall retain jurisdiction over this case until termination of this Consent Decree, for the purpose of resolving disputes arising under this Decree or entering orders modifying this Decree, pursuant to Sections XI and XVIII, or effectuating or enforcing compliance with the terms of this Decree.

XVIII. MODIFICATION

79. The terms of this Consent Decree, including any attached appendices, may be modified only by a subsequent written agreement signed by all the Parties. Where the modification constitutes a material change to this Decree, it shall be effective only upon approval by the Court.

80. Any disputes concerning modification of this Decree shall be resolved pursuant to Section XI (Dispute Resolution), provided, however, that, instead of the burden of proof provided by Paragraph 59, the Party seeking the modification bears the burden of demonstrating that it is entitled to the requested modification in accordance with Federal Rule of Civil Procedure 60(b).

XIX. TERMINATION

81. After Defendant has completed the requirements of Section VI (Compliance Requirements), has thereafter maintained satisfactory compliance with this Consent Decree and Defendant's permit for a period of five years, has complied with all other requirements of this Consent Decree, including those relating to the Section VII (Additional Injunctive Relief), and has paid the civil penalty and any accrued stipulated penalties as required by this Consent Decree, Defendant may serve upon the United States a Request for Termination, stating that

Defendant has satisfied those requirements, together with all necessary supporting documentation.

82. Following receipt by the United States of Defendant's Request for Termination, the Parties shall confer informally concerning the Request and any disagreement that the Parties may have as to whether Defendant has satisfactorily complied with the requirements for termination of this Consent Decree. If the United States agrees that the Decree may be terminated, the Parties shall submit, for the Court's approval, a joint stipulation terminating the Decree.

83. If the United States does not agree that the Decree may be terminated, Defendant may invoke Dispute Resolution under Section XI. However, Defendant shall not seek Dispute Resolution of any dispute regarding termination until 120 Days after service of its Request for Termination.

84. At any time, if the United States has sufficient information to determine that Defendant has met the requirements of termination under Paragraph 81, the United States, after notice to the Defendant, may file a motion to terminate the Decree. If the parties are in agreement, a joint stipulation of termination may be filed with the Court.

85. If the United States does not have sufficient information to determine whether Defendant has met the requirements of termination under Paragraph 81, the United States may request additional information from Defendant, as permitted pursuant to Section XII (Information Collection and Retention), which Defendant shall provide within 30 days of receiving the United States' request.

XX. PUBLIC PARTICIPATION

86. This Consent Decree shall be lodged with the Court for a period of not less than 30 Days for public notice and comment in accordance with 28 C.F.R. § 50.7. The United States reserves the right to withdraw or withhold its consent if the comments regarding the Consent Decree disclose facts or considerations indicating that the Consent Decree is inappropriate, improper, or inadequate. Defendant consents to entry of this Consent Decree without further notice and agrees not to withdraw from or oppose entry of this Consent Decree by the Court or to challenge any provision of the Decree, unless the United States has notified Defendant in writing that it no longer supports entry of the Decree.

XXI. SIGNATORIES/SERVICE

87. Each undersigned representative of Defendant and the Principal Deputy Assistant Attorney General for the Environment and Natural Resources Division of the Department of Justice identified on the DOJ signature page below, certifies that that person is fully authorized to enter into the terms and conditions of this Consent Decree and to execute and legally bind the Party that person represents to this document.

88. This Consent Decree may be signed in counterparts, and its validity shall not be challenged on that basis. Defendant agrees to accept service of process by mail with respect to all matters arising under or relating to this Consent Decree and to waive the formal service requirements set forth in Rules 4 and 5 of the Federal Rules of Civil Procedure and any applicable Local Rules of this Court including, but not limited to, service of a summons. Defendant need not file an answer to the complaint in this action unless or until the Court expressly declines to enter this Consent Decree.

XXII. INTEGRATION

89. This Consent Decree, including deliverables that are subsequently approved pursuant to this Decree, constitutes the entire agreement among the Parties regarding the subject matter of the Decree and supersedes all prior representations, agreements and understandings, whether oral or written, concerning the subject matter of the subject matter of the Decree herein.

XXIII. 26 U.S.C. SECTION 162(f)(2)(A)(ii) IDENTIFICATION

90. For purposes of the identification requirement in Internal Revenue Code Section 162(f)(2)(A)(ii), 26 U.S.C. § 162(f)(2)(A)(ii), and 26 C.F.R. § 1.162-21(b)(2), performance of Section II (Applicability) Paragraph 5; Section VI (Compliance Requirements) Paragraphs 18-23; and Section VII (Additional Injunctive Relief) Paragraphs 24-25, is restitution, remediation, or required to come into compliance with law.

XXIV. HEADINGS

91. Headings to the Sections and Subsections of this Consent Decree are provided for convenience and do not affect the meaning or interpretation of the provisions of this Consent Decree.

XXV. FINAL JUDGMENT

92. Upon approval and entry of this Consent Decree by the Court, this Consent Decree shall constitute a final judgment of the Court as to the United States and Defendant. The Court finds that there is no just reason for delay and therefore enters this judgment as a final judgment under Federal Rules of Civil Procedure 54 and 58.

Dated and entered this ____ day of _____, 2026

UNITED STATES DISTRICT JUDGE

Signature page for Consent Decree in *United States v. Steri-Tech, Inc.* (D. PR)

FOR THE UNITED STATES OF AMERICA:

Date

ADAM R.F. GUSTAFSON
Principal Deputy Assistant Attorney General
Energy and Natural Resources Division
U.S. Department of Justice

JEFFREY
SPECTOR

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JEFFREY A. SPECTOR
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Torre Chardón, Suite 1201
350 Carlos Chardón Street
San Juan, PR 00918
(787) 766-5656

Signature page for Consent Decree in *United States v. Steri-Tech, Inc.* (D. PR)

FOR THE U.S. ENVIRONMENTAL PROTECTION
AGENCY:

PATRICIA
HICK

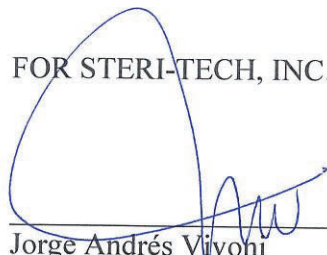
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PATRICIA HICK
Acting Regional Counsel
U.S. Environmental Protection Agency, Region 2
Office of Regional Counsel
290 Broadway, 17th Floor
New York, NY 10007

Signature page for Consent Decree in *United States v. Steri-Tech, Inc.* (D. PR)

8/5/26
Date

FOR STERI-TECH, INC.:



Jorge Andrés Vivoni
Steri-Tech Inc.