

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of:

Medtronic Puerto Rico, Inc.
Villalba, Puerto Rico,

Respondent,

In a proceeding under Section 113(d)
of the Clean Air Act, 42 U.S.C. § 7413(d)

**CONSENT AGREEMENT AND
FINAL ORDER**

CAA-02-2023-1210

A. PRELIMINARY STATEMENT

1. This is an administrative penalty assessment proceeding pursuant to Section 113(d) of the Clean Air Act (the “CAA” or “Act”), 42 U.S.C. § 7413(d), and Sections 22.13 and 22.18 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (“Consolidated Rules”), codified at 40 C.F.R. Part 22.

2. On behalf of the United States Environmental Protection Agency (“EPA” or “Complainant”), the Director of the Caribbean Environmental Protection Division (“CEPD”) for EPA Region 2 is delegated the authority to settle civil administrative penalty proceedings under Section 113(d) of the Act. Specifically, pursuant to EPA Delegation of Authority 7-6-A and EPA Region 2 Delegation of Authority 7-6-A, the EPA Administrator has delegated to the Director of CEPD, through the Regional Administrator of EPA Region 2, the authority to (a) make findings of violations, (b) issue CAA Section 113(d) administrative penalty complaints, and (c) agree to settlements and sign consent agreements memorializing those settlements, for CAA violations that occur in the Commonwealth of Puerto Rico, among other jurisdictions in EPA Region 2.

3. Section 113(d) of the CAA authorizes the EPA Administrator to issue an order assessing civil administrative penalties against any person who has violated or is violating any requirement or prohibition of subchapters I, III, IV-A, V, or VI of the Act, or any requirement or prohibition of any rule, order, waiver, permit, or plan promulgated pursuant to any of those subchapters, including but not limited to any regulation promulgated pursuant to Sections 111, 112, and 114 of the Act, 42 U.S.C. §§ 7411, 7412, and 7414.
4. Pursuant to EPA Delegation of Authority 7-6-C, the EPA Administrator has delegated to the Regional Administrator of EPA Region 2 the authority to execute CAA Section 113(d) Final Orders.
5. Respondent is Medtronic Puerto Rico, Inc. (“Respondent” or “Medtronic”), a corporation doing business in the Commonwealth of Puerto Rico.
6. Respondent is a “person” as defined in Section 302(e) of the Act, 42 U.S.C. § 7602(e).
7. EPA has determined that Medtronic violated the CAA and its implementing regulations promulgated under the CAA. The violations occurred at a Medtronic facility located at PR-149 Km. 56.3, in the municipality of Villalba, Puerto Rico. Specifically, EPA has determined that Medtronic violated the requirements of 40 C.F.R. Part 63, Subpart O, the “Ethylene Oxide Emission Standards for Sterilization Facilities,” promulgated pursuant to Sections 112 and 114 of the CAA, 42 U.S.C. §§ 7412 and 7414. The violations found by EPA are set forth in detail in Section E of this Consent Agreement, entitled “Conclusions of Law.”

B. JURISDICTION

8. This Consent Agreement is entered into pursuant to Section 113(d) of the Act, as amended, 42 U.S.C. § 7413(d), and the Consolidated Rules, 40 C.F.R. Part 22.

9. Pursuant to Section 113(d)(1)(C), the EPA Administrator and the Attorney General, through their respective delegates, have jointly determined that this matter is appropriate for an administrative penalty assessment. *See* 42 U.S.C. § 7413(d)(1)(C); *see also* 40 C.F.R. § 19.4.
10. The Regional Administrator is authorized to ratify this Consent Agreement, which memorializes a settlement between Complainant and Respondent. 40 C.F.R. § 22.18(b)(3).
11. The issuance of this Consent Agreement and attached Final Order simultaneously commences and concludes this proceeding. 40 C.F.R. §§ 22.13(b) and 22.18(b).

C. GOVERNING LAW

National Emissions Standards for Hazardous Air Pollutants – 40 C.F.R. Part 63, Subpart O

12. Section 112 of the Act requires the EPA Administrator to: (i) publish a list of hazardous air pollutants (“HAPs”), (ii) publish a list of categories and subcategories of major and area sources of those HAPs, and (iii) promulgate regulations establishing emissions standards for each such category and subcategory. 42 U.S.C. § 7412(c)(1), (2), and (3).
13. Emissions standards promulgated pursuant to Section 112 are commonly known as National Emissions Standards for Hazardous Air Pollutants (“NESHAPs”). NESHAPs promulgated under the CAA as it existed prior to the 1990 CAA amendments are set forth in 40 C.F.R. Part 61. NESHAPs promulgated under the CAA as amended in 1990 are set forth in 40 C.F.R. Part 63. Part 63 NESHAPs are sometimes known as maximum achievable control technology (“MACT”) standards, because Section 112(d) of the CAA, as amended in 1990, directs EPA to promulgate emissions standards based on the MACT. *See* 42 U.S.C. § 7412(d)(2).
14. Section 112(a) of the Act contains definitions relevant to Section 112. More specifically:
 - a) Section 112(a)(1) of the Act defines “major source” as any stationary source or group of

stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant, or 25 tons per year or more of any combination of hazardous air pollutants.

- b) Section 112(a)(2) of the Act defines “area source” as any stationary source of hazardous air pollutants that is not a major source.
- c) Section 112(a)(3) of the Act defines “stationary source” as any building, structure, facility, or installation which emits or may emit any air pollutant.
- d) Section 112 (a)(4) of the Act defines “hazardous air pollutant” as any air pollutant listed pursuant to Section 112(b) of the Act.
- e) Section 112(a)(9) defines “owner or operator” as any person who owns, leases, operates, controls, or supervises a stationary source.
- f) Section 112(a)(10) defines “existing source” as any stationary source other than a new source.

15. Section 112(i)(3)(A) prohibits the operation of a source in violation of any emissions standard, limitation, or regulation issued pursuant to Section 112, and directs the EPA Administrator to set a compliance deadline for existing sources that is no more than three years after the effective date of the standard.

16. Section 114 of the Act, 42 U.S.C. § 7414, authorizes the EPA Administrator to require testing, monitoring, record-keeping, and reporting of information, to enable him or her to carry out any provision of the Act (except certain provisions in Title II) and to assess compliance with, among other requirements, any regulations promulgated under Section 112 of the Act.

17. Pursuant to Sections 112 and 114 of the Act, 42 U.S.C. § 7412, EPA promulgated the “Ethylene Oxide Emission Standards for Sterilization Facilities,” which are codified at 40 C.F.R.

Part 63, Subpart O, §§ 63.360 *et seq.* (NESHAP Subpart O). *See* 59 Fed. Reg. 62589 (Dec. 6, 1994) (as amended).

18. Pursuant to 40 C.F.R. § 63.360(a), all sterilization sources using 1 ton of ethylene oxide (“EtO”) in sterilization or fumigation operations are subject to the emission standards in 40 C.F.R. § 63.362, except as otherwise specified in 40 C.F.R. § 63.360(b) through (e). Owners or operators of sources using 1 ton of EtO that are subject to the provisions of NESHAP Subpart O must comply with the requirements of 40 C.F.R. Part 63, Subpart A (NESHAP General Provisions), according to the applicability to such sources as specified in Table 1 of 40 C.F.R. § 63.360. *Id.*

19. Pursuant to 40 C.F.R. § 63.362(c), each owner or operator of a sterilization source using 1 ton of EtO shall reduce EtO emissions to the atmosphere by at least 99 percent from each sterilization chamber vent. Pursuant to 40 C.F.R. § 63.362(d), each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent. Pursuant to 40 C.F.R. 63.364(a)(2), each owner or operator of an ethylene oxide sterilization facility subject to these emissions standards shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system. *Id.*

20. Pursuant to 40 C.F.R. 63.354(c), for sterilization facilities complying with 40 C.F.R. § 63.363(b) or (c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with 40 C.F.R. § 63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion

chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature. *Id.*

21. Pursuant to 40 C.F.R. 63.364(c)(4), the owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ± 5.6 °C (± 10 °F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards). *Id.*

NESHAP General Provisions – Recordkeeping and Reporting Requirements

22. 40 C.F.R. § 63.10(e)(3)(i) of the NESHAP General Provisions provides that the owner or operator of an affected source required to install a CMS by a relevant standard shall submit an excess emissions and continuous monitoring system performance report and/or a summary report to the Administrator semiannually.

23. 40 C.F.R. § 63.10(e)(3)(vi) provides that one summary report shall be submitted for the hazardous air pollutants monitored at each affected source (unless the relevant standard specifies that more than one summary report is required, e.g., one summary report for each hazardous air pollutant monitored).

D. FINDINGS OF FACT

24. Respondent owns and operates an ethylene oxide sterilization facility (the "Facility") located at PR-149 Km. 56.3 in Villalba, Puerto Rico.
25. Respondent is a for-profit corporation, incorporated under the laws of and doing business in the Commonwealth of Puerto Rico.
26. The Facility has been in operation since 1998.
27. On June 13, 2000, Respondent submitted to EPA and Puerto Rico Department of Natural and Environmental Resources ("DNER") an initial notification letter stating that the Facility became subject to NESHAP Subpart O on February 16, 2000.
28. The Facility operates under an emission source operating permit, PFE-RG-76-0217-0107-I-II-O, issued by DNER on December 14, 2022, which replaces the previous operating permit that was in effect at the time the alleged violations occurred.
29. On December 6, 2019, EPA Region 2, accompanied by inspectors from the EPA National Enforcement Investigation Center ("NEIC") (collectively "EPA inspectors"), conducted an onsite inspection of the Facility (the "Inspection"). The report of the Inspection was transmitted to the Respondent on June 26, 2020.
30. During the Inspection, the Facility was operating 23 sterilization chambers located in three different areas. Each of the 23 sterilization chambers operated was equipped with an aeration chamber located directly beneath the sterilization chamber and with a catalytic oxidizer abator to control EtO emissions. Each room had a gas chromatograph to measure EtO using a series of sampling ports. Each catalytic oxidizer has a continuous monitoring system (CMS) for measuring the oxidation temperature at the outlet to the catalyst bed.
31. At the time of the Inspection, Respondent had not submitted to EPA the NESHAP Subpart O semi-annual compliance reports required under 40 C.F.R. §§ 63.10(e)(3)(i) and

63.360(a), for the reporting periods of January 1-June 30, 2016; July 1-December 31, 2016; January 1-June 30, 2017; July 1-December 31, 2017; January 1- June 30, 2018; July 1-December 31, 2018; January 1-June 30, 2019; and July 1-December 31, 2019.

32. Following the Inspection, on June 2, 2020, Medtronic submitted to EPA a report dated May 28, 2020, titled "Excess Emissions and Continuous Monitoring System Performance Report and Summary Report: January 1, 2016 through December 31, 2019 Medtronic PR Operations Co."

33. On July 29, 2021, EPA issued to Medtronic a Notice of Violation pursuant to Section 113(a) of the Act. EPA and Medtronic had the opportunity to confer after the issuance of the Notice and Violation and the Respondent submitted additional information that was reviewed by the Agency.

E. CONCLUSIONS OF LAW

Based on the Findings of Fact set forth above, EPA reaches the following Conclusions of Law:

34. Respondent is a "person" within the meaning of Section 302(e) of the Act.

35. Respondent is the owner and operator of the Facility within the meaning of Section 112(a)(9) of the Act and 40 C.F.R. § 63.2.

36. The Facility is subject to the applicable requirements in NESHAP Subpart O and the NESHAP General Provisions.

37. Based on EPA's review of the information provided by Respondent, Respondent's failure to submit an excess emissions and continuous monitoring system performance report and/or summary report to EPA semi-annually for the reporting periods of January 1-June 30, 2016; July 1-December 31, 2016; January 1-June 30, 2017; July 1-December 31, 2017; January 1- June 30,

2018; July 1-December 31, 2018; January 1-June 30, 2019; and July 1-December 31, 2019, is a violation of 40 C.F.R. §§ 63.360 and 63.10(e)(3).

F. TERMS OF CONSENT AGREEMENT

38. For purposes of this proceeding, as required by 40 C.F.R. § 22.18(b)(2), Respondent:
- a. admits that the EPA has jurisdiction over the subject matter alleged in this Consent Agreement;
 - b. neither admits nor denies the factual allegations and alleged violations of law stated in sections A through E above;
 - c. consents to the assessment of a civil penalty as stated below;
 - d. consents to the conditions specified in this Consent Agreement;
 - f. consents to any stated “permit action” (as that term is defined in 40 C.F.R. § 22.3(a) of the Consolidated Rules), as applicable; waives any right to contest the conclusions of law set forth in Section E of this Consent Agreement; and
 - f. waives its right to appeal the Final Order accompanying this Consent Agreement.
39. For purposes of this proceeding, Respondent:
- a. agrees that this Consent Agreement states a claim upon which relief may be granted against Respondent;
 - b. acknowledges that this Consent Agreement constitutes an enforcement action for purposes of considering Respondent’s compliance history in any subsequent enforcement actions;
 - c. consents to the issuance of the attached Final Order;
 - d. waives any and all remedies, claims for relief, and otherwise available rights to judicial or administrative review that Respondent may have with respect to any

issue of fact or law set forth in this Final Order, including any right of judicial review under Section 307(b)(1) of the Clean Air Act, 42 U.S.C. § 7607(b)(1);

- e. consents to personal jurisdiction in any action to enforce this Consent Agreement or Final Order, or both, in the United States District Court for the District of Puerto Rico; and
- f. waives any rights it may possess at law or in equity to challenge the authority of the EPA to bring a civil action in a United States District Court to compel compliance with the Consent Agreement or Final Order, or both, and to seek an additional penalty for such noncompliance, and agrees that federal law shall govern in any such civil action.

Civil Penalty

- 40. Pursuant to Section 113(d) of the Act, 42 U.S.C. § 7413(d), Respondent shall pay the civil penalty of \$117,998 (“EPA Penalty”) within 30 calendar days of the effective date specified in Section H of this Consent Agreement (“Effective Date”). Respondent shall pay the EPA Penalty using a method provided on the website <http://www2.epa.gov/financial/additional-instructions-making-payments-epa>, identifying each and every payment with “Docket No. CAA-02-2023-1210.” Within 24 hours of payment of the EPA Penalty, Respondent shall send proof of payment according to the instructions contained in the paragraph directly below.
- 41. Proof of payment and any other written notices to be provided by this Order shall be submitted to:

Nancy Rodríguez, Chief
Multimedia Permits and Compliance Branch
Caribbean Environmental Protection Division
U.S. Environmental Protection Agency - Region 2
City View Plaza II – Suite 7000
#48 Road. 165 Km. 1.2
Guaynabo, Puerto Rico 00968-8073

rodriguez.nancy@epa.gov

and

Liliana Villatora, Chief, Air Branch
Office of Regional Counsel
U.S. Environmental Protection Agency – Region 2
290 Broadway – 16th Floor
New York, New York 10007
villatora.liliana@epa.gov

42. “Proof of payment” means, as applicable, a copy of the check, confirmation of credit card or debit card payment, or confirmation of wire or automated clearinghouse transfer in the amount due, identified with “Docket No. CAA-02-2023-1210,” and any other information required to demonstrate that payment has been made according to the applicable payment method.

43. If Respondent fails to timely pay the full amount of the EPA Penalty assessed under this Consent Agreement, the EPA may:

- a. request the Attorney General to bring a civil action in an appropriate district court to recover: the amount assessed; interest at rates established pursuant to 26 U.S.C. § 6621(a)(2); the United States’ enforcement expenses; and a 10 percent quarterly nonpayment penalty, pursuant to 42 U.S.C. § 7413(d)(5);
- b. refer the debt to a credit reporting agency or a collection agency, or the Department of Justice, pursuant to 42 U.S.C. § 7413(d)(5); 40 C.F.R. §§ 13.13, 13.14, and 13.33;
- c. collect the debt by administrative offset (*i.e.*, the withholding of money payable by the United States to, or held by the United States for, a person to satisfy the debt the person owes the Government), which includes, but is not limited to, referral to the Internal Revenue Service for offset against income tax refunds, pursuant to 40 C.F.R. Part 13, Subparts C and H; and

- d. suspend or revoke Respondent's licenses or other privileges, or suspend or disqualify Respondent from doing business with the EPA or engaging in programs the EPA sponsors or funds, pursuant to 40 C.F.R. § 13.17.

G. EFFECT OF CONSENT AGREEMENT AND ATTACHED FINAL ORDER

44. In accordance with 40 C.F.R. § 22.18(c), completion of the terms of this Consent Agreement and Final Order resolves only Respondent's liability to the United States for federal civil penalties for the violations specifically alleged above.
45. Penalties paid pursuant to this Consent Agreement shall not be deductible for purposes of federal taxes.
46. This Consent Agreement constitutes the entire agreement and understanding of the parties and supersedes any prior agreements or understandings, whether written or oral, among the parties with respect to the subject matter hereof.
47. The terms, conditions, and compliance requirements of this Consent Agreement may not be modified or amended except upon the written agreement of both parties, and approval of the Regional Administrator or other delegate.
48. Any violation of this Consent Agreement and Final Order may result in EPA pursuing a civil judicial action for an injunction or civil penalties of up to \$109,024 per day per violation, or both, as provided in Section 113(b)(2) of the Act, 42 U.S.C. § 7413(b)(2) (as adjusted for inflation pursuant to 40 C.F.R. § 19.4), as well as criminal sanctions, as provided in Section 113(c) of the Act, 42 U.S.C. § 7413(c). The EPA may use any information submitted under this Consent Agreement and Final Order in an administrative, civil judicial, or criminal action. Respondent reserves and may assert any available argument and defense, and may use any information submitted under this Consent Agreement and Final Order, in response to any such action pursued by the EPA.

49. Nothing in this Consent Agreement shall relieve Respondent of the duty to comply with all applicable provisions of the Act and other federal, state, or local laws or statutes, nor shall it restrict the EPA's authority to seek compliance with any applicable laws or regulations, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state, or local permit.

50. Nothing herein shall be construed to limit the power of the EPA to undertake any action against Respondent or any person in response to conditions that may present an imminent and substantial endangerment to the public health, welfare, or the environment.

51. The EPA reserves the right to revoke this Consent Agreement and settlement penalty if and to the extent that the EPA finds, after signing this Consent Agreement, that any information provided by Respondent was materially false or inaccurate at the time such information was provided to the EPA. The EPA reserves the right to assess and collect any and all civil penalties for any violation described herein. Under such circumstance, Respondent reserves the right to assert any available argument and defense to any such claim by the EPA. The EPA shall give Respondent notice of its intent to revoke, which shall not be effective until received by Respondent in writing.

H. EFFECTIVE DATE

52. Respondent and Complainant agree to issuance of the attached Final Order. Upon filing, the EPA will transmit a copy of the filed Consent Agreement to the Respondent. This Consent Agreement and attached Final Order shall become effective after execution of the Final Order by the Regional Administrator, on the date of filing with the Hearing Clerk.

I. SIGNATURES

The foregoing Consent Agreement in the Matter of Medtronic Puerto Rico, Inc., Docket No. CAA-02-2023-1210, is Hereby Stipulated, Agreed, and Approved for Entry.

FOR RESPONDENT:

DocuSigned by:


Graham Phillips
Vice-President on behalf of
Medtronic Puerto Rico, Inc.
Road 149 Km. 56.3
Call Box 6001
Villalba, PR 00766

3/27/2023

Date

FOR COMPLAINANT:



Carmen R. Guerrero Pérez
Director
Caribbean Environmental Protection Division
U.S. Environmental Protection Agency - Region 2

APRIL 11 / 2023

Date

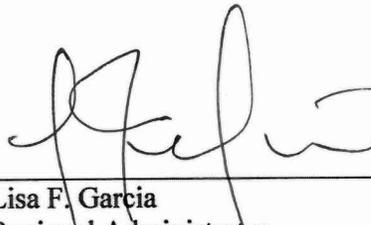
In the Matter of Medtronic Puerto Rico Inc.
CAA-02-2023-1210

FINAL ORDER

Pursuant to 40 C.F.R. § 22.18(b) of the EPA's Consolidated Rules of Practice and Section 113(d) of the Clean Air Act, 42 U.S.C. § 7413(d), the Regional Administrator of EPA Region 2 concurs in the foregoing Consent Agreement, *In the Matter of Medtronic Puerto Rico, Inc.*, CAA-02-2023-1210. The attached Consent Agreement resolving this matter, entered into by the parties, is incorporated by reference into this Final Order and is hereby approved, ratified, and issued.

The Respondent is ORDERED to comply with all terms of the Consent Agreement, effective immediately.

SO ORDERED.



Lisa F. Garcia
Regional Administrator
United States Environmental Protection Agency
Region 2
290 Broadway, 26th Floor
New York, New York 10007-1866

DATE: 4/13/23

