



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION
CITY VIEW PLAZA II BUILDING, 7TH FLOOR
ROUTE 165 GUAYNABO, PUERTO RICO 00968

August 10, 2023

SENT VIA EMAIL

Medtronic Puerto Rico Operation Company - Humacao
909 MARIANA WARDS KM 0.4
HUMACAO, PUERTO RICO 00792.

C/O: Mr. Arnaldo Rivera

Emails: rivera25@medtronic.com, ramosv24@medtronic.com, agonzalez@vhapr.com

RE: RCRA § 3008 – NOTICE OF VIOLATION
Medtronic Puerto Rico Operation Company - Humacao
EPA ID: PRD000692681
CEPD-RCRA-23-0000-3008-009

Dear Mr. Rivera:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901 et seq. Pursuant to RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), EPA promulgated rules, regulations, and standards governing the handling and management of hazardous waste as set forth in 40 Code of Federal Regulations (C.F.R.) Parts 260-272. For the purposes of this Notice of Violation (NOV), the hazardous waste regulations governing the generation of hazardous waste were promulgated in 1980 and amended by HSWA in 1984. The Commonwealth of Puerto Rico is not authorized by the EPA to conduct a hazardous waste program and to enforce RCRA under Section 3006 of RCRA, 42 U.S.C. § 6926.

On or about May 18, 2023, a duly authorized representative of the EPA conducted a Compliance Evaluation Inspection (CEI) of Medtronic Puerto Rico Operation Company, located in Humacao, Puerto Rico, (the “Facility”) pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. As a result of the CEI, EPA representative found the Facility in violation of §§ 262.17(a)(5)(i)(B), 262.261(d), and 262.261(e) of the RCRA Regulations.

This Notice of Violation (Enclosure I) is issued pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by RCRA and HSWA, 42 U.S.C. §§ 6901 and 6928. Issuance of this NOV and compliance with its terms does not preclude EPA from taking formal enforcement action against you and/or your company, including a monetary penalty, under Section 3008 of RCRA, 42 U.S.C. § 6928, or any other applicable regulation or statute.

If you have not already done so, you must take immediate action to correct the violations described in Enclosure I. Please submit, within thirty (30) days of the receipt of this letter, a response which includes (1) a description of the actions you have taken to correct the violations noted in Enclosure I, (2) documentation that the violations have been corrected, and (3) a description of the procedures that will be

Internet Address (URL) • <http://www.epa.gov>

CEPD-RCRA-16-0372

put into place to prevent such violations from occurring in the future. For consistency, please provide your answers in a format which is keyed to the sections as outlined in Enclosure I to this letter.

Your response to this NOV can be send through email to the following email address caballer.rosana@epa.gov and can also be mailed to the following address:

Rosana Caballer-Cruz, Enforcement Officer
Response and Remediation Branch
U.S. Environmental Protection Agency - Region 2
Caribbean Environmental Protection Division
City View Plaza II, suite 7000
#48 PR-165 km 1.2
Guaynabo, PR 00968-8069

Failure to respond in full to the above requirements may result in federal enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. If you have any questions regarding this matter, please contact Ms. Rosana Caballer-Cruz, from my staff, at 787-977-5880 or via e-mail at caballer.rosana@epa.gov.

Sincerely,

CARMEN
GUERRERO PEREZ

Digitally signed by
CARMEN GUERRERO PEREZ
Date: 2023.08.10 12:41:11
-04'00'

Carmen R. Guerrero Pérez
Director

Enclosures: Enclosure I - Notice of Violation

cc: Ms. Lorna Rodríguez, RCRA Enforcement Section Chief
Puerto Rico Dept. Natural and Environmental Resources



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION
CITY VIEW PLAZA II BUILDING, 7TH FLOOR
ROUTE 165 GUAYNABO, PUERTO RICO 00968

ENCLOSURE I – RCRA § 3008 NOTICE OF VIOLATION

Medtronic Puerto Rico Operation Company
EPA ID: PRD000692681
CEPD-RCRA-23-0000-3008-009

On or about May 18, 2023, a duly authorized representative of EPA conducted a Resource Conservation and Recovery Act (RCRA) Hazardous Waste Compliance Evaluation Inspection (CEI) of the MEDTRONIC PUERTO RICO OPERATION COMPANY (Medtronic) located at 909 MARIANA WARDS KM 0.4, HUMACAO, PUERTO RICO, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. As a result of the CEI, EPA has identified the following violations of the RCRA regulations.

i. 40 C.F.R. § 262.17(a)(5)(i)(B)

At the time of the inspection, Medtronic failed § 40 C.F.R. § 262.17(a)(5)(i)(B) which required “*An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704)...*”

The facility failed to comply with this requirement in the Manufacturing Area and at the 90-day Hazardous Waste Accumulation Area (HWAA). At the Manufacturing Area, the 55-gallon containers observed at both SAAs Subareas did not have available a pictographic label, and/or indication of the hazards. This observation was also raised with the two (2) 55-gallon containers observed at the 90-day Hazardous Waste Accumulation Area (HWAA), which none of them had available a pictographic label, and/or indication of the hazards.

ii. 40 C.F.R. § 262.261(d)

At the time of the inspection, Medtronic failed § 262.261(d) which required “*The plan must list names and emergency telephone numbers of all persons qualified to act as emergency coordinator (see § 262.264), and this list must be kept up to date...*”

The facility failed to comply with this requirement. During the documents review section, one of the facility’s emergency response phone numbers was not up to date.

iii. 40 C.F.R. § 262.261(e)

At the time of the inspection, Medtronic failed § 262.261(e) which required *“The plan must include a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities.”*

The facility failed to comply with this requirement. The document evaluated did not have available the location of all the facility’s emergency equipment.