



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.