26 August 2024

Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333

Re: Revised Chapter 428 Stewardship Program for Packaging, Additional Draft Rule Comments

Siemens Medical Solutions USA, Inc., on behalf of itself and its Siemens Healthineers affiliates – including Siemens Healthcare Diagnostics Inc. and Varian Medical Systems, Inc. – (collectively Siemens Healthineers), respectfully submits comments to the Maine Department of Environmental Protection during the additional comment period for the Draft Rule of the Extended Producer Responsibility Program for Packaging.

Siemens Healthineers prides itself on pioneering breakthroughs in healthcare for everyone sustainably. We manufacture and service a broad range of medical devices and components, including diagnostic imaging devices, in vitro diagnostics (IVD) tests and analyzers, devices to treat cancer through radiation, clinical information systems, IT systems and related hardware and software. Siemens Healthineers also manages and services multi-vendor devices on behalf of hospitals, clinics, and other health care providers.

Siemens Healthineers is required to adhere to strict packaging requirements to ensure compliance with federal and international regulations, including requirements specified by the FDA (Food and Drug Administration) and the DOT (Department of Transportation)/IATA (International Air & Transport Association) for the ground/air shipment of Dangerous Goods. These regulatory requirements are designed to protect public health and safety in the transportation, storage and use of medical devices. The regulations include, but are not limited to:

Federal Laws/Regulations and International Standards impacting Siemens Healthineers product packaging
Medical Device Regulations/ISO Certification • FDA 21 CFR 820.130 Device Packaging • ISO 13485:2016 7.5.11 Preservation of Product **Transportation/Dangerous Goods Regulations** • 49 CFR 173 Shippers – General Requirements for Shipments and Packagings / United Nations Recommendations on the Transport of Dangerous Goods • 49 CFR 173.185 Lithium Cells and Batteries / IATA DGR 3.9.2.6 Lithium Batteries • 49 CFR 173.24 General Requirements for Packaging and Packages / IATA DGR 5.0.2 General Packaging Requirements • 49 CFR 173.301 General Requirements for Shipment of Compresses Gases and other Hazardous Materials in Cylinders, UN Pressure Receptacles, and Spherical Pressure Vessels / IATA DGR 5.2 Packaging Instructions, PI 200 – Packing Instruction 200 / IATA DGR 6.4 Compressed Gases • 49 CFR 178 Specifications for Packagings / IATA DGR 6.3 UN Packaging Performance Tests • 49 CFR 178.516 Standards for Fiberboard Boxes / IATA DGR 6.2.12 Fiberboard Boxes

While the Maine Department of Environmental Protection's rule proposal includes welcomed changes to overall sustainability goals, the draft rules do not provide needed exemptions for packaging of medical devices. We believe it is critical to exempt these types of products and supporting equipment to ensure continued patient care in clinical laboratory and diagnostic imaging settings.

Packaging for medical device and components should be exempted for two key reasons. First, the highly regulated nature of this market requires extensive certification processes and prolonged testing periods, especially for IVD products, making any reworking of packaging a process that takes a minimum of 7 years to complete. Second, medical devices generally (and Siemens Healthineers' products specifically) require a high variety of packaging materials per shipment due to the sale of highly individualized products, making it exceptionally challenging to standardize or alter packaging without risking delays or compromising product integrity. Therefore, an exemption is essential to avoid disruptions in patient care.

Siemens Healthineers commends the state of Maine for its focus on sustainability and would welcome a collaboration to work with us as we continue to be an industry leader in sustainability in the medical device and IVD product space. Our sustainability strategy is built on three pillars: We are focused on improving healthcare access for all, limiting our environmental impact as we pioneer breakthroughs, and engaging our diverse Siemens Healthineers to achieve this impact on a global scale. We pioneer breakthroughs in healthcare. For everyone. Everywhere. Sustainably.

Sincerely,

David Pacitti
Head, Americas Region
Siemens Healthineers