



**U.S. Customs and
Border Protection**

N352105

August 29, 2025

CLA-2-90:OT:RR:NC:N3:135

CATEGORY: Classification

TARIFF NO.: 9019.20.0000; 9817.00.96

Robert Leo
Meeks, Sheppard, Leo & Pillsbury LLP
570 Lexington Avenue, Ste. 2405
New York, NY 10022

RE: The tariff classification of a specialized printed circuit board assembly for CPAP sleep therapy devices from Thailand

Dear Mr. Leo:

In your letter dated August 6, 2025, you requested a tariff classification ruling on behalf of Philips RS North America LLC. Additional information was provided via email on August 20 and August 29, 2025.

The item under consideration is a specialized printed circuit board assembly (PCBA), part number 1124507, designed exclusively for the Philips DreamStation™ CPAP Sleep Therapy devices. The DreamStation devices provide continuous airway pressure (CPAP) and Bilevel Positive Airway Pressure (BiPAP) therapy to treat patients with obstructive sleep apnea. You state that the PCBA is used exclusively to run all functionality of the devices. You also claim that the PCBA is designed to fit and function with only the DreamStation devices and cannot be used with other devices.

The applicable subheading for the PCBA will be 9019.20.0000, Harmonized Tariff Schedule of the United States (HTSUS), which provides for “[o]zone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; parts and accessories thereof.” The general rate of duty will be free.

Effective April 5, 2025, Executive Orders implemented “Reciprocal Tariffs.” All imported merchandise must be reported with either the Chapter 99 provision under which the reciprocal tariff applies or one of the Chapter 99 provisions covering exceptions to the reciprocal tariffs. At this time products of Thailand will be subject to an additional 19 percent ad valorem rate of duty. At the time of entry, you must report the Chapter 99 heading applicable to your product classification, i.e. 9903.02.61, in addition to subheading 9019.20.0000, HTSUS, listed above.

However, the additional duties imposed by subheading 9903.02.61 shall not apply to goods for which entry is properly claimed under a provision of chapter 98 of the tariff schedule pursuant to applicable regulations of

U.S. Customs and Border Protection (“CBP”), and whenever CBP agrees that entry under such a provision is appropriate, except for goods entered under heading 9802.00.80; and subheadings 9802.00.40, 9802.00.50, and 9802.00.60.

In your submission you requested consideration of a secondary classification under 9817.00.96, HTSUS, which applies to articles and parts and accessories of articles specifically designed or adapted for the use or benefit of the permanently or chronically physically or mentally handicapped.

Subheading 9817.00.96, HTSUS, covers: “[a]rticles specially designed or adapted for the use or benefit of the blind or other physically or mentally handicapped persons; parts and accessories (except parts and accessories of braces and artificial limb prosthetics) that are specially designed or adapted for use in the foregoing articles: [o]ther.”

The term “blind or other physically or mentally handicapped persons” includes “any person suffering from a permanent or chronic physical or mental impairment which substantially limits one or more major life activities, such as caring for one’s self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, or working.” U.S. Note 4(a), Subchapter XVII, Chapter 98, HTSUS. Subheading 9817.00.96, HTSUS, excludes “(i) articles for acute or transient disability; (ii) spectacles, dentures, and cosmetic articles for individuals not substantially disabled; (iii) therapeutic and diagnostic articles; or, (iv) medicine or drugs.” U.S. Note 4(b), Subchapter XVII, Chapter 98, HTSUS.

In *Sigvaris, Inc. v. United States*, 227 F. Supp 3d 1327, 1336 (Ct. Int’l Trade 2017), aff’d, 899 F.3d 1308 (Fed. Cir. 2018), the U.S. Court of International Trade (CIT) explained that “specially” means “to an extent greater than in other cases or towards others” and “designed” means something that is “done, performed, or made with purpose and intent often despite an appearance of being accidental, spontaneous, or natural.” We must first evaluate “for whose, if anyone’s, use and benefit is the article specially designed,” and then, whether “those persons [are] physically handicapped [].” *Sigvaris*, 899 F.3d at 1314. The Court of Appeals for the Federal Circuit (CAFC) clarified in *Sigvaris*, 899 F.3d at 1314-15 that to be “specially designed,” the merchandise “must be intended for the use or benefit of a specific class of persons to an extent greater than for the use or benefit of others” and adopted the five factors used by U.S. Customs and Border Protection:

- (1) the physical properties of the article itself (i.e., whether the article is easily distinguishable by properties of the design, form, and the corresponding use specific to this unique design, from articles useful to non-handicapped persons); (2) whether any characteristics are present that create a substantial probability of use by the chronically handicapped so that the article is easily distinguishable from articles useful to the general public and any use thereof by the general public is so improbable that it would be fugitive; (3) whether articles are imported by manufacturers or distributors recognized or proven to be involved in this class or kind of articles for the handicapped; (4) whether the articles are sold in specialty stores which serve handicapped individuals; and, (5) whether the condition of the articles at the time of importation indicates that these articles are for the handicapped.

Customs and Border Protection has determined that the CPAP devices designed for the treatment of obstructive sleep apnea qualify for duty-free treatment under subheading 9817.00.96, HTSUS. See NY ruling N059778 (dated May 29, 2009). Online research found that BiPAP devices are used to treat sleep apnea, particularly when CPAP therapy is not sufficient or well-tolerated. CPAP machines deliver the same pressure when breathing in and breathing out. BiPAP machines provide two different pressure levels, one level of air pressure during inhalation and a lower level for exhalation. You state that the PCBA is an indispensable part for the devices to assist sleep apnea impaired person. It is specially designed for and marketed for the DreamStation devices. Based on the information provided and the precedent, it is our opinion that the PCBA is a part of the DreamStation CPAP Sleep Therapy devices without which the devices cannot function and thus is eligible for duty-free treatment under subheading 9817.00.96, HTSUS.

The tariffs and additional duties cited above are current as of this ruling's issuance. Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided at <https://hts.usitc.gov/>.

The holding set forth above applies only to the specific factual situation and merchandise description as identified in the ruling request. This position is clearly set forth in Title 19, Code of Federal Regulations (CFR), Section 177.9(b)(1). This section states that a ruling letter is issued on the assumption that all of the information furnished in the ruling letter, whether directly, by reference, or by implication, is accurate and complete in every material respect. In the event that the facts are modified in any way, or if the goods do not conform to these facts at time of importation, you should bring this to the attention of U.S. Customs and Border Protection (CBP) and submit a request for a new ruling in accordance with 19 CFR 177.2. Additionally, we note that the material facts described in the foregoing ruling may be subject to periodic verification by CBP.

This ruling is being issued under the provisions of Part 177 of the Customs and Border Protection Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, please contact National Import Specialist Fei Chen at fei.chen@cbp.dhs.gov.

Sincerely,

(for)

Denise Faingar
Acting Director
National Commodity Specialist Division