U.S. Department of Homeland Security
U.S. Customs and Border Protection
National Commodity Specialist Division
One World Trade Center, Suite 51.201
New York, NY 10007

U.S. Customs and Border Protection

N356471

December 19, 2025

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

CATEGORY: Classification

TARIFF NO.: 9817.00.96

Tan Albayrak
Reed Smith LLP
1 Blossom Yard,
London E16RS
United Kingdom

RE: The eligibility of EMG needle electrodes under the Nairobi Protocol treatment from Ireland

Dear Mr. Albayrak:

In your letter dated November 26, 2025, you requested a tariff classification ruling on behalf of your client, Natus Medical Inc. Additional information was provided by email dated December 16 and December 17, 2025.

TECA® Elite Disposable Concentric Needle Electrodes and Dantec® DCN™ Disposable Concentric Needle Electrodes are available in various styles. Each of these electrodes consists of a sharp, silicone coated stainless-steel cannula with three-bevel tip design, a precisely centered tungsten core (insulated wire), a polyesterimide insulator separating the cannula and core, a color-coded hub with a recording area direction indicator, a hub cover, and a protective tube. These needle electrodes are connected to an electromyography (EMG) device through a cable and designed for EMG examinations. They are intended for use with recording, monitoring, and stimulation equipment for capturing biopotential signals, including electromyographic and muscle potential signals.

TECA® MyoJect Disposable Luer Lock Needle Electrodes and Bo-ject® DHN Disposable Needle Electrodes are available in different styles. Each comprises a stainless-steel hypodermic needle coated with an insulator, a Luer lock or slip tip connector, a color-coded lead wire with a connector, and a protective tube. These electrodes are designed for recording EMG activity while allowing injection of medication.

TECA® Elite Disposable Monopolar Needle Electrodes are offered in various styles. Each consists of a coated stainless-steel needle and a color-coded hub. They are packaged with a reusable lead cable. They are connected to an EMG device via the cable and designed for EMG examinations. They are intended for use with recording, monitoring and stimulation equipment for capturing biopotential signals, including electromyographic and muscle potential signals.

You state that the subject EMG needle electrodes are specially engineered for EMG and nerve conduction studies procedures performed uniquely for the diagnosis, monitoring, and management of chronic neuromuscular impairments. EMG and nerve condition studies are ordered specifically for individuals suffering from long-term neuromuscular diseases, muscular dystrophy, peripheral neuropathies, radiculopathies, motor neuron disease, and other permanent or chronic impairments affecting muscle function. The general public has no conceivable use for EMG needles, which cannot perform injections, draw fluids, or accomplish any general medical purpose. Their utility exists only within neurodiagnostic settings and only when paired with EMG equipment and other specialized equipment. Natus, the manufacturer of these needles, is internationally known for manufacturing diagnostic systems and consumables used exclusively in neurodiagnostic, rehabilitative, and chronic impairment evaluation spaces. The company does not manufacture general consumer medical products, and their portfolio is devoted to diagnostic testing and neurological patient care. The needles discussed herein are sold directly to hospitals, and in most cases Veterans Affairs-run hospitals. Each needle is individually packaged for single use, pre-sterilized, and labeled exclusively for its purpose, with technical specification markers for appropriate handling by professionals. The labeling and presentation communicate clearly that the merchandise is suitable only for diagnosis of chronic neuromuscular disease and not for general medical use.

In your submission you requested consideration of a classification under 9817.00.96, HTSUS, which applies to articles and parts 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: "Articles 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 . . . Other." 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 (CBP):

> (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.

Online research indicates that EMG and nerve conduction studies (NCS) are electrodiagnostic procedures designed to measure the electrical activity of muscles and nerves. EMG measures the electrical activity within muscles, both at rest and during contraction, using a needle electrode. NCS, on the other hand, measures the speed and strength of electrical signals as they travel along nerves, typically utilizing a surface electrode (which is not part of this ruling request). These tests are valuable tools for diagnosing health conditions that may have damaged muscles or nerves, or impaired their coordinated function. While they can be performed independently, EMG and NCS are commonly conducted together. The EMG needle electrodes are specifically used in conjunction with EMG devices for these electrodiagnostic procedures. Consequently, given that U.S. Note 4(b) to Subchapter XVII of Chapter 98 explicitly excludes diagnostic articles from subheading 9817.00.96, HTSUS, the instant EMG needle electrodes are ineligible for duty-free treatment under HTSUS 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)

Evan Conceicao
Designated Official Performing the Duties of the Division Director
National Commodity Specialist Division