



## **DEPARTMENT OF HOMELAND SECURITY**

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

#### **Notice of Issuance of Final Determination Concerning Wound Therapy System**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determination.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of the PICO single use negative pressure wound therapy system manufactured and distributed by Smith & Nephew. Based upon the facts presented, CBP has concluded that the United Kingdom will be the country of origin of the PICO single use negative pressure wound therapy system (“PICO NPWT System”) for purposes of U.S. Government procurement.

**DATE:** The final determination was issued on June 30, 2015. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within [insert 30 days from date of publication in the Federal Register].

**FOR FURTHER INFORMATION CONTACT:** Antonio J. Rivera, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202) 325-0226.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on June 30, 2015 pursuant to subpart B of part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP has issued a final determination concerning the country of origin of the PICO NPWT System manufactured and distributed by Smith & Nephew, which may be offered to the U.S. Government under an undesignated government procurement contract. This final

determination, HQ H259473, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreement Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, under the totality of the circumstances, considering the PICO NPWT System's use as a single medical instrument, the origin of the dressings, and the flash programming and final assembly of the pump, which will be performed in the U.K., and will change the pump into a specialized pump that can only be used with its respective dressings, CBP concluded that the country of origin of the PICO NPWT System will be the United Kingdom for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: June 30, 2015

Harold Singer,  
Acting Executive Director,  
Regulations and Rulings,  
Office of International Trade.

HQ H259473

June 30, 2015

OT:RR:CTF:VS H259473 AJR

CATEGORY: Origin

Daniel S. Char, Esq.

Associate General Counsel (Commercial)  
Smith and Nephew, PLC  
150 Minuteman Road  
Andover, MA 01810

RE: Trade Agreements Act; Government Procurement; Country of Origin of the PICO Single Use Negative Pressure Wound Therapy System

Dear Mr. Char:

This is in response to your letter, dated November 19, 2014, requesting a final determination on behalf of Smith & Nephew, PLC (“Smith & Nephew”), pursuant to subpart B of part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of Smith & Nephew’s PICO Single Use Negative Pressure Wound Therapy System (“PICO NPWT System”). As the manufacturer and U.S. importer, Smith & Nephew is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination. In addition, we have reviewed and grant the request for confidentiality pursuant to 19 C.F.R. § 177.2(b)(7), with respect to certain information submitted.

**FACTS:**

The PICO NPWT System is a sterile, single-use, complete negative pressure wound therapy system consisting of a pump, two dressings with attached long tube assemblies, and retention strips. It is marketed for use in a sterile operating room environment. Each dressing is applied to the wound and held in place with the retention strips. The long tube assembly is attached to the dressing on one end, and to the PICO pump on the other end, connecting them together. The suction pump pulls air out of the dressing via the long tube assembly, creating negative pressure and drawing excess fluid from the wound into the dressing. The pump is battery powered and delivers 80 mmHg of continuous negative pressure for up to seven days, after which it is programmed to permanently stop working. Consistent with the lifespan of the pump, the dressings provide a total of seven days wear time. The pump in the PICO NPWT System can only be used with the dressings included in the system, and will only be used once by a patient for a specific wound type as the therapy prescribes. The dressings are only sold with the pump and not separately available. Unlike conventional negative pressure systems that use canisters for the collection of wound fluid, the PICO NPWT System is canister-less, which according to your submission means that the components of the PICO NPWT System can only be used together as a system.

The pump in the PICO NPWT System consists of: a printed circuit board (“PCB”) assembly that provides pressure measurement and feedback control for the pump; a diaphragm pump and motor that provide airflow to maintain pressure; components such as an internal air path and check valve; a plastic housing; and, batteries. Most of the pump’s components are made in China, except for a lightweight pipe, valve and connector made in the U.S., and the batteries. The pump components and subassemblies will be shipped from China to the United Kingdom (“U.K.”) for the remainder of the pump manufacturing process. In the U.K., U.S.-origin firmware, written and validated in the U.S. according to medical device and Food and Drug Administration standards, will be loaded onto the pump at flash programming stations. The flash programming stations are equipped with “bed of nails” interfaces, which have discrete electrical conductors that extend and make contact with discrete pads on the PCB assembly. You state that the erasable programmable read-only memory (“EPROM”) on the PCB assembly is actively programmed by sending electric charges through the “bed of nails” to the PCB assembly in order to drive the EPROM into receptive mode, and then sending byte by byte to program the EPROM with the unique calibrations and specific parameters required to operate the pump.<sup>1</sup> You state that this process requires moderate, semi-skilled technicians trained in “clean-room” techniques and operating programming fixtures. The pump is then fully assembled by assembling the subassemblies with the case pieces and attaching the battery cover and label, which you state requires low, basic “box build” assembly techniques. After assembly, the pump goes through a series of tests to verify calibrated performance of the device, which you state requires moderate, semi-skilled technicians operating test fixtures.

You state that the firmware is essential to the function of the pump because the firmware ensures that the pump dispenses the accurate amount of negative pressure. You state that while the components used to manufacture the PICO NPWT System are largely generic (e.g. micro-controllers, small battery powered motors and generic PCB assemblies), it is only when the pump is calibrated and then flashed with specific firmware that it becomes a true medical device, as the flashing enables the pump to deliver calibrated, therapeutic negative pressure levels to the wound.

You state that the material, labor, and overhead costs of the PICO NPWT System are broken down per country as follows: [XXXX]% from the pump and battery production in China, [XXXX]% from flashing and final assembly in the U.K., and the remaining [XXXX]%<sup>2</sup> mainly from the U.K.

The dressings are manufactured in the U.K., with materials of U.K. and Canadian origin,<sup>3</sup> to produce a four-layer dressing that consists of: (1) a high moisture vapor transfer rate (“MTVR”) film to allow for transpiration of the wound fluid; (2) a superabsorbent layer to hold the fluid; (3) an airlock layer to ensure consistent delivery of negative pressure from the pump to the wound bed; and, (4) an adhesive layer to maintain an effective seal around the dressing and prevent trauma. The manufacturing operations to produce the dressings involve extruding

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<sup>1</sup> You state that, though EPROM is not irreversible, re-programming EPROM requires working through different levels of encryption and the use of specific equipment, which is not readily available.

<sup>2</sup> [XXXX]% derives from the production of the dressing in the U.K. Aside from [XXXX]% for primary sterile barrier costs from both the U.K. and [XXXX], the remaining costs will be incurred in the U.K.

<sup>3</sup> All of the layers, except for the super-absorbent layer that is from Canada, are from the U.K.

medical grade film, perforating the adhesive layer to ensure breathability of the dressing, and then shaping, cutting and laminating together the layers of the dressing. The four-layer dressing is then connected to a long tube assembly, which is also manufactured in the U.K. from U.K.-origin materials. The dressings and pumps are then sterilized, separately sealed, packed, and then re-sterilized. Once the PICO NPWT System is received by its user, the user will connect the pump to the dressing by the attached long tube assembly.

You state that a majority of the essential therapeutic elements for wound healing are delivered via the unique dressing. You state that the dressing is the fundamental “enabling technology,” as the combination of layers work together to: manage the wound fluid; ensure consistent delivery of negative pressure from the pump to the wound bed (stimulating blood vessel and cell growth); and, maintain an optimal environment for wound healing by protecting the wound from outside contaminants and limiting disruption of the wound bed, which allows for the formation of granulation tissue.

The PICO NPWT System is imported into the United States packaged for retail sale. Its main components, the pump and the dressings, are not assembled together and must be connected to each other by the user after the dressing is secured to the patient with the retention strips. You state that, as imported, the PICO NPWT System is classified in subheading 9018.90.80, Harmonized Tariff Schedule of the United States (“HTSUS”), as a medical instrument. You also state that it is described by two of the American Medical Association Current Procedural Terminology (“CPT”) codes, G0456 and G0457, which provide for: “negative pressure wound therapy (e.g. vacuum assisted drainage collection) using a [...] device, not durable medical equipment, including provision of [...] dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session.” According to your submission, the difference in the codes is based on the description of the size of the wound to be treated.

#### ISSUE:

What is the country of origin of the PICO NPWT System for purposes of U.S. Government procurement?

#### LAW AND ANALYSIS:

Pursuant to Subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In determining whether the combining of parts or materials constitutes a substantial transformation, the determinative issue is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article. *Belcrest Linens v. United States*, 573 F. Supp. 1149 (Ct. Int'l Trade 1983), *aff'd*, 741 F.2d 1368 (Fed. Cir. 1984). Assembly operations that are minimal or simple, as opposed to complex or meaningful, will generally not result in a substantial transformation. *See* C.S.D. 80-111, C.S.D. 85-25, C.S.D. 89-110, C.S.D. 89-118, C.S.D. 90-51, and C.S.D. 90-97. If the manufacturing or combining process is a minor one which leaves the identity of the article intact, a substantial transformation has not occurred. *Uniroyal, Inc. v. United States*, 3 CIT 220, 542 F. Supp. 1026 (1982), *aff'd* 702 F. 2d 1022 (Fed. Cir. 1983).

In order to determine whether a substantial transformation occurs when components of various origins are assembled into completed products, CBP considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Additionally, factors such as the resources expended on product design and development, the extent and nature of post-assembly inspection and testing procedures, and worker skill required during the actual manufacturing process will be considered when determining whether a substantial transformation has occurred. No one factor is determinative.

In this case, the PICO NPWT System is comprised of the pump and the dressings. These two components are attached to each other by the user and together, these two components are used as one product to extract fluid from the wound. The four-layer dressing is manufactured in the U.K. by combining MTRV film from the U.K. to allow for transpiration of the wound fluid, a superabsorbent layer from Canada to hold the fluid, an airlock layer from the U.K. to ensure consistent delivery of negative pressure from the pump to the wound bed, and an adhesive layer from the U.K. to effectively seal the dressing. The long tube assembly, which is produced in the U.K. from U.K. materials, is adhered to the dressing in the U.K. and is later connected by the user to the pump to create a one-way vacuum via a unique taper-lock connector that ensures the pump and dressing can only connect to each other and not to other medical connectors. The pump is as important as the dressing in allowing negative pressure to be created and to enable fluid to be drawn from the wound. Therefore, the additional processes performed on the pump component are necessary in order to find that the PICO NPWT System is a product of the U.K.

You argue that the PICO NPWT System should be considered a product of the U.K. because the U.K is the country of origin of the dressings, and that although the pump

components and subassemblies will be made in China, the pump will be flash programmed with firmware and the final assembly of the pump will take place in the U.K. You state that the pump will be programmed with U.S.-origin firmware at flash programming stations equipped with “bed of nails” interfaces, which have discrete electrical conductors that extend from the “bed of nails” and make contact with discrete pads on the PCB assembly.<sup>4</sup> You state that the EPROM is actively programmed because this process sends electric charges through the “bed of nails” to the PCB assembly in order to drive the EPROM into receptive mode, and then sends byte by byte to program the EPROM with the unique calibrations and specific parameters required to operate the pump.<sup>5</sup> You state that, though the EPROM is not irreversible, re-programming the EPROM requires working through different levels of encryption and the use of specific equipment, which is not readily available.<sup>6</sup> Accordingly, you state that only when the pump is calibrated and flashed with specific firmware, it becomes a true medical device, as the flashing enables the pump to deliver calibrated, therapeutic negative pressure levels to the wound. In support of your positions you cite Headquarters Ruling (“HQ”) H034843, dated May 5, 2009; and HQ 968000, dated February 14, 2006.

HQ H034843 concerned the country of origin of USB flash drives that used software and firmware developed in Israel and an assembly process that began in China and ended in Israel or the United States. CBP noted that the assembly in Israel or the United States, mainly the installation and customization of the firmware and software, made the USB flash drives functional, permitted them to execute their security features, and increased their value. Therefore, the USB flash drives were substantially transformed in the countries where these

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<sup>4</sup> “Bed of nails” refers to a traditional electronic fixture with numerous pins extending from the fixture to make contact with points on a PCB. Pressing a PCB against a “bed of nails” interface allows the PCB to be directly accessed for programming. See Michael J. Smith, *Why Program Devices at In-Circuit Test?*, EVALUATION ENGINEERING, at <http://www4.evaluationengineering.com/articles/201110/why-program-devices-at-in-circuit-test.php> (specifically the “bed of nails” explanation); see also “In-Circuit Test,” WIKIPEDIA, at [http://en.wikipedia.org/wiki/In-circuit\\_test](http://en.wikipedia.org/wiki/In-circuit_test) (only with reference to “Bed of Nails tester” section).

<sup>5</sup> EPROM refers to a non-volatile memory that retains its contents until it is exposed to ultraviolet light, and it is programmed by using a specialized machine to force an electric charge that sends bits of the EPROM onto a PCB. See G. Groeseneken, et al., *Basics of Nonvolatile Semiconductor Memory Devices*, 25 – 28, at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.111.9431&rep=rep1&type=pdf>; see also Integrated Circuit Engineering Corporation, *ROM, EPROM, and EEPROM Technology*, 4 – 9, at <https://web.eecs.umich.edu/~prabal/teaching/eecs373-f10/readings/rom-eprom-eprom-technology.pdf>.

<sup>6</sup> EPROM is not easily reprogrammed because, even when the reprogramming change is minimal, the process requires erasing the memory by exposing the EPROM to ultraviolet light, and then reprogramming it byte by byte. See *id.*

operations took place, making the country of origin for the USB flash drives either Israel or the United States.

In HQ 968000, CBP ruled that the country of origin for marking purposes of a fabric switch for storage area networks was the United States. The assembly of the hardware for the switch occurred in China. Then, the resulting electromechanical assembly was shipped to the United States, where U.S.-origin software was installed, configured, and tested. *See also Data General v. United States*, 4 Ct. Int'l Trade 182 (1982).

As in HQ H034843 and HQ 968000, the firmware will be installed in a different country from where the majority of the product is assembled, thereby imparting the product (here, the pump) with an essential and required feature (here, enabling the pump to operate as a unique medical device). However, despite these similarities, HQ H034843 and HQ 968000 concerned a USB flash drive and a switch for network storage, which are instruments primarily associated with computer-related products, while in this case the product is primarily a medical instrument and serves separate functions apart from the programmed capabilities. For instance, in HQ H215657, dated April 29, 2013, CBP held that a flashlight originated from China despite the fact that it was programmed in the U.S. with U.S. software. HQ H215657 explained that the programming was not essential to the basic operation of the flashlight, as it only enhanced how the flashlight operated, without changing its fundamental nature. Though such programming provided the flashlight with some additional features, CBP held that the programming was not sufficiently complex to change the identity or characterize the device.

Nonetheless, to the extent that the programming process in the U.K. is integrated with the U.K.-origin dressing to produce a specific-use medical device, we find that the last substantial transformation of the PICO NPWT System occurs in the U.K. The unique dressing is the “enabling technology” that provides the essential therapeutic elements for wound healing (e.g. fluid management, protecting against contaminants, and limiting wound bed disruption) to the instrument. Furthermore, the programmed pressure calibrations are critical to the pump’s function as a medical device, and can only tolerate a small margin for error since any programming error would devalue the pump for medical purposes and require correction via a difficult reprogramming technique.

Based on the information in your request, under the totality of the circumstances, considering the PICO NPWT System’s use as a single medical instrument, the origin of the dressings, and the flash programming and final assembly of the pump, which will be performed in the U.K, and will change the pump into a specialized pump that can only be used with its respective dressings, we find that the country of origin of the PICO NPWT System will be the United Kingdom for purposes of U.S. Government procurement.

#### HOLDING:

Based on the facts in this case, we find that the country of origin of the PICO NPWT System will be the United Kingdom for purposes of U.S. Government procurement.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final

determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Harold Singer, Acting Executive Director  
Regulations and Rulings  
Office of International Trade

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