



## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Issuance of Final Determination Concerning Biomedix Selec-3 Multiple Drop Intravenous Product

**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 Biomedix Selec-3 Multiple Drop Intravenous Product. Based upon the facts presented, CBP has concluded that the subject IV products, under two of five scenarios, would be the product of a foreign country or instrumentality designated pursuant to title III of the Trade Agreements Act of 1979, as amended; in three of the scenarios, the last substantial transformation occurs in the United States.

**DATES:** The final determination was issued on May 13, 2025. 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 no later than [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**FOR FURTHER INFORMATION CONTACT:** Ani Mard, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325-0727.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on May 13, 2025, U.S. Customs and Border Protection (CBP) issued a final determination concerning the country of origin of the Biomedix Selec-3 Multiple Drop Intravenous Product, for purposes of title III of the Trade Agreements Act of 1979. This final determination, HQ H339462, was issued at the request of Wai Medical Technologies LLC, under procedures set forth at 19 CFR part 177, subpart B, which implements title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP has concluded that, based upon the facts presented, the country of origin of the IV products is the country in which the selectable drop chamber (“SDC”) originates.

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*.

**Alice A. Kipel,**  
*Executive Director,*  
*Regulations and Rulings,*  
*Office of Trade.*

**HQ H339462**

**May 13, 2025**

**OT:RR:CTF:VS H339462 AM**

**CATEGORY:** Origin

Dave Townsend  
Dorsey & Whitney LLP  
50 South Sixth Street Suit 1500  
Minneapolis, Minnesota 55402

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. 2511); Subpart B, Part 177, CBP Regulations; Country of Origin of IV Drips

Dear Mr. Townsend:

This is in response to your request, dated May 16, 2024, on behalf of your client, Wai Medical Technologies (“Wai Medical”) and its affiliate MedSource International LLC (“MedSource”), for a final determination concerning the country of origin of the Biomedix Selec-3 Multiple Drop Intravenous Product (“Selec-3 IV Product”), pursuant to Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. 2511 *et seq.*), and subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 CFR 177.21, *et seq.*). Your request, submitted as an electronic ruling request, was forwarded to this office from the National Commodity Specialist Division (“NCSD”). Wai Medical is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and 177.23(a) and is therefore entitled to request this final determination.

**FACTS:**

The merchandise at issue is the Selec-3 IV Product. The Selec-3 IV Product is an intravenous set made with components from a variety of U.S. and non-U.S. components. The Selec-3 IV Product has a patented selectable drop chamber (“SDC”) that offers three drop settings. These settings allow the user to adjust the drip rate for the fluids administered via the Selec-3 IV Product. By allowing the user to quickly and easily change the drip rate, the Selec-3 IV Product saves time, reduces inventory costs, and minimizes the risk of contamination of fluids administered to patients.

The Selec-3 IV Product has the following components:

- Check valve and connector: allows opening and closing the polyvinyl chloride (“PVC”) tube for purposes of helping regulate flow of the fluid and allows control of fluid from either the Drop Chamber or one of the Y-sites.
- Dust cap: placed on the end of the Selec-3 IV Product to ensure the end remains uncontaminated prior to use.
- Pinch Clamp (x2): The pinch clamps can be used to stop and start the flow of liquid through the tubing and to the patient.
- PVC Tube (73 Inches): The PVC tube allows the fluid to flow from the bag containing the fluid, through the SDC, and ultimately to the patient.

- Roller Clamp: The clamp is a binary control allowing or disallowing flow of fluid into the SDC, and thus to the patient.
- SDC: The SDC is a clear plastic tube with a mechanism allowing the user to select one of three drop rates. The SDC is patented and allows unwanted gas to bubble out of the fluid, allowing medical staff to see that fluid is flowing through the IV, and allowing regulation of the flow rate through the patented adjustable SDC.
- Spike and Cap: The spike is used to connect the Selec-3 IV Product to the fluid being administered to the patient. The spike is inserted into the bag holding the fluid. The cap is used to ensure the spike is not contaminated prior to use.
- Spin Lock: The spin lock allows connection between a device allowing the direct infusion of the fluids into the patient to the Selec-3 IV Product.
- Y-Sites (x3): The Y-sites allow the injection of additional treatments or medicines to be administered to the patient, in addition to the fluid connected to the Selec-3 IV Product that runs through the SDC and tubing to the patient.

Assembly of the Selec-3 IV Product involves three steps: (1) assembly of the SDC subassembly with the roller clamp and spike, (2) the assembly of the other tubing sub-assemblies, and (3) the final assembly.

#### (1) Assembly of the SDC

Assembly of the SDC involves connecting, gluing, and sealing the parts of the SDC, including the tubing and the roller clamp and spike. The plastic tubing is inspected and the tube to the drip-rate selector is aligned and glued. Then, the drop chamber is inspected and cured with ultraviolet light to bind them together. The assembler must apply silicone to the selector, sealing the selector, and adding the selector top. Lastly, the chamber is connected to a short piece of tubing that ends with a roller clamp and spike. The total cost of the SDC sub-assembly components is roughly less than half of the total cost of the Selec-3 IV Product.

#### (2) Assembly of the other tubing sub-assemblies

The premanufactured parts are inspected for defects. Assembly continues with three sections of tubing, i.e., the primary tubing, the patient side assembly (top half), and the extension set (bottom half). To assemble each of those three sections, tubing is connected to luers and Y-sites.

#### (3) Final Assembly

During the final assembly process, the primary tubing, the patient side assembly, and the extension set are put together with the SDC sub-assembly, and the Selec-3 IV Product is complete. Adhesives are added to ensure lasting connection between certain parts.

Set forth below are several sourcing scenarios for components that Wai Medical is contemplating. Wai Medical requests that CBP issue a determination covering all five scenarios below.

Scenario 1: All of the Selec-3 IV Product components originate from the United States, are sterilized in the United States, and then are assembled in India prior to being re-imported, and fully assembled in the United States.

Scenario 2: The SDC originates from the United States and is assembled into the SDC sub-assembly (including the roller clamp and spike) in the United States. The remaining components originate, are sterilized, and assembled in India. The final assembly takes place in India.

Scenario 3: The SDC originates from the United States. The SDC sub-assembly takes place in India. Additionally, remaining components originate, are sterilized, and assembled in India. The final assembly takes place in India.

Scenario 4: The SDC originates from Mexico and all components (including SDC) are sterilized and assembled in India. All of the Selec-3 IV Product components, except the SDC, originate and are sterilized in non-TAA eligible countries. The final assembly takes place in India.

Scenario 5: The SDC components originate and are assembled into the SDC sub-assembly in Mexico. All other parts of the Selec-3 IV Product originate from China. Sterilization of the entire product occurs in China. The final assembly takes place in India.

## ISSUE:

What is the country of origin of the Biomedix Selec-3 Multiple Drop Intravenous Product for purposes of U.S. Government procurement?

## LAW & ANALYSIS:

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 purpose of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 CFR 177.21 *et seq.*, which implements Title III, Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-2518).

CBP’s authority to issue advisory rulings and final determinations is set forth in 19 U.S.C. 2515(b)(1), which states:

For the purposes of this subchapter, the Secretary of the Treasury shall provide for the prompt issuance of advisory rulings and final determinations on whether, under section 2518(4)(B) of this title, **an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title.**

Emphasis added.

The Secretary of the Treasury’s authority mentioned above, along with other customs revenue functions, are delegated to the Secretary of Homeland Security via Treasury Department Order (TO) 100-20 “Delegation of Customs revenue functions to Homeland Security,” dated October 30, 2024, and are subject to further delegations to CBP (*see also* 19 CFR Part 177, subpart B).

The rule of origin set forth in 19 U.S.C. 2518(4)(B) states:

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 CFR 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Acquisition Regulation (“FAR”). *See* 19 CFR 177.21. In this regard, CBP recognizes that the FAR restricts the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 CFR 25.403(c)(1).

The FAR, 48 CFR 25.003, defines “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States 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 transformed.

Additionally, the FAR, 48 CFR 25.003, defines “designated country end product” as:

a WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

Section 25.003 defines “WTO GPA country end product” as an article that:

- (1) Is wholly the growth, product, or manufacture of a WTO GPA country; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country 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 transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

Once again, we note that the Selec-3 IV components are sourced from both the United States, TAA-designated countries (*i.e.*, Mexico), as well as non-TAA countries (*i.e.*, China, Vietnam, and Malaysia).

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.

Assembly operations that are minimal or simple, as opposed to complex or meaningful, will generally not result in a substantial transformation. Factors which may be relevant in this evaluation include the nature of the operation (including the number of components assembled), the number of different operations involved, and whether a significant period of time, skill, detail, and quality control are necessary for the assembly operation. *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. *See Uniroyal, Inc. v. United States*, 3 CIT 220, 542 F. Supp. 1026 (1982), *aff'd*, 702 F.2d 1022 (Fed. Cir. 1983) (imported shoe uppers added to an outer sole in the United States were the “very essence of the finished shoe” and the character of the product remained unchanged and did not undergo substantial transformation in the United States).

The U.S. Court of International Trade (“CIT”) more recently interpreted the meaning of “substantial transformation” in *Energizer Battery, Inc. v. United States*, 190 F. Supp. 3d 1308 (2016). *Energizer* involved the determination of the country of origin of a flashlight, referred to as the Generation II flashlight. All the components of the flashlight were of Chinese origin, except for a white LED and a hydrogen getter. The components were imported into the United States and assembled into the finished Generation II flashlight. The *Energizer* court reviewed the “name, character and use” test utilized in determining whether a substantial transformation had occurred and noted, citing *Uniroyal, Inc.*, 3 CIT at 226, that when “the post-importation processing consists of assembly, courts have been reluctant to find a change in character, particularly when the imported articles do not undergo a physical change.” *Energizer* at 1318. In addition, the court noted that “when the end-use was pre-determined at the time of importation, courts have generally not found a change in use.” *Energizer* at 1319.

In reaching its decision, the *Energizer* court expressed the question as one of whether the imported components retained their names after they were assembled into the finished Generation II flashlights. The court found “[t]he constitutive components of the Generation II flashlight do not lose their individual names as a result [of] the post-importation assembly.” The court also found that the components had a predetermined end-use as parts and components of a Generation II flashlight at the time of importation and did not undergo a change in use due to the post-importation assembly process. Finally, the court did not find the assembly process to be sufficiently complex as to constitute a substantial transformation. Thus, the court found that *Energizer*’s imported components did not undergo a change in name, character, or use as a result of the post-importation assembly into a finished Generation II flashlight. Virtually all of the components of the Generation II flashlight, including the most important component, the LED, were of Chinese origin. Accordingly, the court determined that China was the correct country of origin of the Generation II flashlights for purposes of government procurement.

In Headquarters Ruling Letter (“HQ”) 734617, dated August 17, 1993, CBP considered an IV device for administering fluid and found that the foreign-made tubing assembly with the U.S.-assembled patented pump system in California resulted in a substantial transformation and determined the United States to be the country of origin. The U.S.-assembled patented pump system performed the product’s most important function, i.e., to regulate and ensure that the proper amount of intravenous medication gets to the patient. Notably, more than 75 percent of the value of the finished article was attributable to the U.S. operations.

Additionally, in HQ 734006, dated March 25, 1991, CBP held that U.S.-origin components of a medical device used to administer liquid nutritional preparations are not substantially transformed by assembly in Mexico. The value added in Mexico accounted for less than 10 percent of the direct cost of manufacturing the subject merchandise, and it contained no

materials of Mexican origin. Accordingly, CBP determined there was no change in the name, character, or use of the assembled components as this process constituted a simple assembly.

In HQ 560613, dated October 28, 1997, CBP held that U.S.-origin components were not substantially transformed in Ireland when made into a pregnancy test kit. The test kit was made from the following U.S. components: top and bottom housing, paper, antibody, wick, laminate, and nitrocellulose. In addition, a splash guard from Ireland and rayon from Germany were used. The critical components of the pregnancy test kit were found to be the three U.S.-origin antibodies. CBP recognized that the U.S.-origin components imparted the essential character of the pregnancy test kit and that the simple assembly of placing the antibodies onto the rayon membrane, and subsequent assembly of the strips into a plastic housing did not result in a substantial transformation. Lastly, in HQ H035441, dated September 11, 2008, CBP found that the assembly and sterilization processes performed in Costa Rica to create the LAP-BAND® SYSTEM AP II were relatively simple and, therefore, the operations did not result in a substantial transformation of the components. *See also* HQ 561167, dated December 14, 1998.

In the case at hand, the SDC is patent-protected, and we find that it performs the most critical function of the Selec-3 IV product, i.e., regulating the drip rate of the fluid being administered to the patient. Importantly, the SDC sub-assembly consisting of the SDC plus the roller clamp and the spike represents the single most significant portion of the cost of materials of the Selec-3 IV Product. Here, similar to HQ 734617, the SDC imparts the essential character of the Selec-3 IV product because it serves the product's most important function. Additionally, sterilization only represents a small portion of the total cost of production of the subject merchandise. Consistent with HQ H035441, we find that the sterilization process should not result in substantial transformation.

Based on the information presented, we find that in Scenarios One, Two, and Three, the last substantial transformation occurs in the United States and therefore, the Selec-3 IV Product is not a product of a foreign country or instrumentality designated pursuant to 2511(b) of this title (*i.e.*, China, Vietnam, and Malaysia). As to whether the Selec-3 IV Product produced in the United States qualifies as a "U.S.-made end product" under Scenarios One, Two, and Three, you may wish to consult with the relevant government procuring agency and review *Acetris Health, LLC v. United States*, 949 F.3d 719 (Fed. Cir. 2020). Furthermore, we find that the country of origin of the Selec-3 IV Product in Scenarios Four and Five is Mexico and, therefore is a product of a foreign country or instrumentality designated pursuant to 2511(b) of this title.

#### **HOLDING:**

Based on the information presented, we find that in Scenarios One, Two, and Three, the last substantial transformation of the Biomedix Selec-3 Multiple Drop Intravenous Product occurs in the United States. Furthermore, we find that the country of origin in Scenarios Four and Five is Mexico.

Notice of this final determination will be given in the *Federal Register*, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 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 U.S. Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director  
Regulations & Rulings  
Office of Trade

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