DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Certain Carbon Dioxide Sampling Line Products

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 certain carbon dioxide sampling line products known as "FilterLine" and "CapnoLine." Based upon the facts presented, CBP has concluded that Israel is the country of origin for purposes of U.S. Government procurement.

DATES: The final determination was issued on July 8, 2014. 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: Grace A. Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202) 325-7941.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on July 8, 2014 pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of certain carbon dioxide sampling line products known as "FilterLine" and "CapnoLine," which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H248851, was issued 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 concluded that, based upon the facts presented, the assembly operations performed in China, using Israeli components, do not substantially transform the sampling line components. Therefore, the country of origin is Israel 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: July 8, 2014.

Sandra L. Bell,
Executive Director,
Regulations and Rulings,
Office of International Trade.

Attachment

HQ H248851

July 8, 2014

OT:RR:CTF:VS H248851 GaK

CATEGORY: Origin

Michelle L. Butler
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005

RE: U.S. Government Procurement; Country of Origin of FilterLine Set and CapnoLine; Substantial Transformation

Dear Ms. Butler:

This is in response to your letter, dated November 6, 2013, requesting a final determination on behalf of Oridion Medical 1987 Ltd. ("Oridion"), 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. Your letter was forwarded to this office by the National Commodity Specialist Division on December 12, 2013. By letters dated February 19, May 15, and May 28, 2014, additional explanation was provided for our consideration in connection with the request for a final determination.

This final determination concerns the country of origin of Oridion's carbon dioxide sampling lines, specifically the FilterLine Set Adult/Pediatric ("FilterLine") and the Smart CapnoLine H Plus O_2 ("CapnoLine"). We note that as a foreign manufacturer of the products at issue, Oridion 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. Photographs were submitted with your request.

FACTS:

The products at issue are referred to as carbon dioxide ("CO_2") sampling lines: medical devices designed to carry a patient's breath to a monitor. Each sampling line includes tubing, a means of connecting to the patient, referred to as the patient interface, and a means of connection to a monitor.

These sampling lines are classified into two product families: (1) The Filterline set sampling lines for intubated patients, designed to connect to ventilator tubing carrying oxygenated air from a ventilator to a patient through an airway adaptor, and (2) the Capnoline sets for non-intubated patients, which provide a nasal or oral/nasal "interface" for the patient.

FilterLine

The components of the FilterLine include:

1) CO_2 tube (manufactured in Israel and cut to length in China),
2) Universal Airway Adapter (manufactured in China), and
3) Quick Seal Connector (itself assembled in China using an Israeli origin Quick Seal Filter Housing, Chinese origin Hollofiber and an end connector called the Quick Seal LD Orange Golden).

The Hollofiber is a fiber membrane filter that prevents liquids, particles, or bacteria from reaching the monitor which can contaminate the breath sample. The Hollofiber is placed inside the Quick Seal Filter Housing, which is connected to the Quick Seal LD Orange Golden. The Universal Airway Adapter is connected to the CO_2 tube and the Quick Seal Connector is adhered to the other end of the CO_2 tube.

The CO_2 tube delivers the patient's breath to the monitor, which you claim is the essential function of the finished product. The tube is of a patented design. In order to prevent blockage from mucus and blood, the tube must be able to handle moisture in a very precise manner. In addition, the tube's diameter cannot be too narrow, which would increase the likelihood of blockage, or too wide, which would create a delay in measurements. The FilterLine is assembled in China. It is then sent to Israel for quality control, final inspections, and packaging.

CapnoLine

The components of the CapnoLine include:

1) CO_2 tube (manufactured in Israel and cut to length in China),
2) Cannula, which is connected to the patient (manufactured in Israel), 3) Quick Seal Connector (itself assembled in China using an Israeli origin Quick Seal Filter Housing, Chinese origin Hollofiber and an end connector called the Quick Seal LD Yellow Golden),
4) O_2 tube (manufactured in Israel and cut to length in Israel),
5) Miscellaneous tubing (manufactured in Israel),
6) Nafion dryer, used to reduce the humidity of the breath (manufactured in the U.S.),
9) connector/slides to hold the O_2 and CO_2 tubing in place (manufactured in China).

In China, the cannula is connected to the Nafion dryer on the right side and to the tubing on the left side. The other end of the Nafion dryer is attached to the CO_2 tube. The CO_2 tube and the miscellaneous tubing from the Cannula are held together with a connector/slide and connected to the O_2 tube. Then, the Quick Seal Connector, is attached to the end of the CO_2 tube.

As with the FilterLine, the CO_2 tube and in this case the O_2 tube deliver the patient's breath to the monitor, which you claim is the essential function of the finished product. The finished CapnoLine is sent to Israel for quality control and packaging.

LAW AND ANALYSIS:

Pursuant to Subpart B of Part 177, 19 CFR § 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 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. No one factor is decisive, the key 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. Additionally factors such as the resources expended on product design and development, extent and nature of post-assembly inspection and testing procedures, and the degree of skill required during the actual manufacturing process may be relevant when determining whether a substantial transformation has occurred.

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 was 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.

FilterLine

You believe that the country of origin of the FilterLine is Israel because it is the country in which the CO_2 tube was manufactured. We agree that the CO_2 tube performs the essential function of the finished product, which is the delivery of breath for monitoring the CO_2 level in a patient's breath. The assembly process in China consists of cutting to length and attaching the CO_2 tube

with four other components from Israel and China. Under the described assembly process, the CO_2 tube is attached to other components that facilitate its function and it does not lose its individual identity. Consistent with HQ 560613, we find that the Israel-origin CO_2 tube is not substantially transformed by the cutting to length and assembly operations performed in China to produce the FilterLine. We conclude, based upon these specific facts, that the country of origin of the FilterLine for purposes of U.S. Government procurement is Israel.

CapnoLine

You believe that the country of origin of the CapnoLine is Israel because it is the country in which the CO_2 tube and O_2 tube were manufactured. As with the FilterLine, the CO_2 tube and O_2 tubes in the CapnoLine perform the essential function, which is the delivery of breath for monitoring the CO_2 level in a patient's breath while delivering O_2 to the patient. The assembly process in China consists of cutting to length and connecting the CO_2 tube to several different components from Israel, U.S. and China by inserting components and adhering them with a solvent. The CO_2 tube is not physically altered, aside from being cut to length. Based on the information before us, and consistent with HQ 560613, we find that the Israel-origin CO_2 tube and the O_2 tube impart the essential character of the CapnoLine and is not substantially transformed by the assembly operations performed in China. We note that the Cannula and Quick Seal Filter Housing are also of Israeli origin. Therefore, based upon these specific facts, the country of origin of the CapnoLine for purposes of U.S. Government procurement is Israel.

HOLDING:

The FilterLine and the CapnoLine are not substantially transformed when they are assembled in China with Israeli and U.S. components. As a result, the country of origin of Oridion's sampling lines, specifically the FilterLine and the CapnoLine, for purposes of U.S. Government procurement is Israel.

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,

Sandra L. Bell, Executive Director
Regulations and Rulings
Office of International Trade

[FR Doc. 2014-16424 Filed 07/11/2014 at 8:45 am; Publication Date: 07/14/2014]