[BILLING CODE 9111-14]

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Catheter Trays

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 Foley catheter trays to be offered to the U.S. Government under an undesignated government procurement contract. The final determination found that based upon the facts presented, the country of origin of the subject trays is China and U.S.A.

DATES: The final determination was issued on June 30, 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 30 days of [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

FOR FURTHER INFORMATION CONTACT: Fernando Peña, Esq., Valuation and Special Programs Branch, Office of International Trade; telephone (202) 325-1511.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on June 30, 2014, pursuant to subpart B of part 177, Customs Regulations (19 CFR part 177, subpart B), CBP issued a final

determination concerning the country of origin of certain Foley catheter trays to be offered to the U.S. Government under an undesignated government procurement contract. The final determination, Headquarters Ruling Letter H230416, was issued at the request of Medline Industries, Inc., 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 processing in Mexico of several medical instruments and accessories to create the subject "Foley catheter trays" does not constitute a substantial transformation into a product of Mexico for purposes of U.S. government procurement.

Section 177.29, Customs Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, Customs 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, 2014.

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

Attachment

HQ H230416

June 30, 2014

OT:RR:CTF:VS H230416 FP

CATEGORY: Marking

Mr. Michael T. Shor
Arnold & Porter, LLP
555 12th Street, NW
Washington, DC 20004

RE: U.S. Government Procurement; Final Determination; Country of origin of catheter system trays; substantial transformation; 19 CFR Part 177

Dear Mr. Shor:

This is in response to your letter on behalf of Medline Industries, Inc. (hereinafter "Medline"), in which you seek a final determination pursuant to subpart B of Part 177, Customs Regulations, 19 CFR 177.21 et seq. Under these regulations, which implement Title III of the Trade Agreements Act of 1979, as amended, (19 U.S.C. § 2411 et seq.), U.S. Customs and Border Protection ("CBP") issues country of origin advisory rulings and final determinations on whether an article is or would be a product of a designated foreign 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.

This final determination concerns the country of origin of six models of Foley catheter trays, which Medline is considering selling to the U.S. Government in an unspecified procurement tender. We note that Medline is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and is entitled to request this final determination.

FACTS:

According to your submission and information provided, Medline developed its Foley catheter trays (hereinafter "trays") to aid in the prevention of catheter-associated urinary tract infections. Medline designed sterilized, single-use trays containing a catheter and all of the equipment necessary to insert the catheter, organized and sequenced in a way to

minimize the possibility of infection. You state that each tray is intended to be used only as an entirety, for single use, after which use the individual components, other than the inserted catheter that remains in the patient, are discarded.

You state that Medline manufactures six different models of the tray, which differ principally in the materials used for the catheter. The main model sold is the silicone-elastomer coated latex Foley catheter tray. Medline also produces two latex-free models, including a 100% silicone model, and a silicone catheter with silver ions bound in the catheter's coating. Each of these three types comes in two sizes, 16Fr and 18Fr, using the industry standard French units (FR), where 1 Fr is equivalent to 0.33 mm of diameter. You state that the six tray models are otherwise similar.

With your correspondence, you provided a representative sample of the latex Foley model, together with a detailed description and a list of medical instruments and accessories (materials and components) placed into the tray. These include patient drapes, hand sanitizer, sterile gloves, a syringe prefilled with sterile water to inflate the catheter balloon, lubricating jelly, iodine swabsticks, a syringe to draw a urine sample, securement devices, and a specimen jar. In the sample, these instruments are arranged in a plastic tray, which contains indentations to hold items or group of items.

The medical instruments and accessories are sourced from China and the U.S., and imported into Mexico, where they are placed into trays, packaged, and boxed at Medline's facility in Nuevo Laredo, Mexico. Specifically for the latex Foley catheter tray, the specimen container, catheter Foley silver, gloves, and drainage bag are manufactured in China. The remaining materials are of U.S. origin.

The catheter is sourced in varying countries depending on the model. The silicone and latex catheters (as in the submitted sample of the latex Foley catheter tray) are manufactured in China. Silvertouch catheters are manufactured in India or Canada. For all models, the catheter and drainage bag are packaged together in Mexico, together with all of the medical instruments and materials needed to insert and secure the catheter, including materials to create a sterile field. The accessories of the other models and their origin were not provided.

You claim that all of the instruments and materials in the tray are intended to be used in conjunction with the insertion of the catheter, in a specific sequence, and only for one use, and thus function together as a single medical device. After their initial use, all of the included instruments and materials, as well as the instructions and plastic tray, are discarded and have no alternative use.

According to Medline the tray components are delivered to a clean room and put together by a designated line of approximately 15 specially trained technicians. The catheter is attached to the drain bag in a way that creates a closed urological system that minimizes contamination when the catheter is used on the patient. By connecting the catheter to the drain bag in Medline's sterile environment, instead of having a nurse connect the two in a hospital room environment, the risk of bacterial contamination and patient infection is minimized.

You claim that attaching the drain bag is a fundamental characteristic of a Foley catheter system, and that the design of the tray transforms the components into an assembly which promotes proper insertion of the Foley catheter, thereby minimizing patient risk. After packaging, Medline performs a quality inspection prior to wrapping, sealing and packaging operations in Mexico, before sending the finished trays for medical sterilization in the United States.

ISSUE:

Whether Medline's Foley catheter system management trays are considered to be products of Mexico for purposes of U.S. Government procurement.

LAW AND ANALYSIS:

Under subpart B of part 177, 19 CFR 177.21 et seq., which implements Title III of the Trade Agreements Act of 1979, as amended ("TAA"; 19 U.S.C. 2511 et seq.), CBP issues country of origin advisory rulings and final determinations on 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 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 Procurement Regulations. See 19 CFR 177.21. In this regard, CBP recognizes that the Federal Procurement Regulations restrict 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).

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. Unites States, 573 F. Supp. 1149 (CIT 1983), aff'd, 741 F.2d 1368 (Fed. Cir. 1984). CBP considers the totality of the circumstances and makes such decisions on a case-by-case basis. The country of origin of the article's components, extent of the processing that occurs within a given country, and whether such processing renders a product with a new name, character, or use are primary considerations in such cases. Additionally, facts such as resources expended on product design and development, extent and nature of post-assembly inspection procedures, and worker skill required during the actual manufacturing process will be considered when analyzing whether a substantial transformation has occurred; however, no one such factor is determinative.

In Headquarters Ruling Letter (HRL) 555268 dated March 6, 1991, Customs considered the eligibility for preferential tariff treatment under the Generalized System of Preferences to "Code 6000 Infection Control Systems." Similar to the articles under consideration, the Code 6000 catherization tray contained the following items packaged together: latex catheter, "Mono-Flo" drainage bag, lubricating jelly, latex gloves, fenestrated

drape, underpad prefold, urine specimen vial, forceps, applicator rayon balls, prefilled 10 cubic centimeter syringe, a tamper band, and a package of povidone iodine solution. The tray contained sections and indentations for individual items. The paper cover of the tray, which was designed to be peeled off, listed the contents and the directions for use. Customs determined that the catheter of Malaysian origin imparted the essential character to the set and, therefore, the Code 6000 combination package was classified in subheading 9018.39.00, HTSUS. As in this case, with respect to the Code 6000 combination package, certain items in the set were imported into Mexico from the U.S. or other sources and merely packaged together with items of Mexican origin. Customs held that merely packaging the items originating outside of Mexico with items of Mexican origin clearly did not result in a substantial transformation of the non-Mexican items into "products of" that country. Therefore, because the entire imported entity (the set) was not the "product of" Mexico, as required by the GSP statute, neither the set nor any part thereof would be entitled to duty-free treatment under the GSP. As to the U.S. items in the set, it was determined that they were eligible for duty-free treatment under subheading 9801.00.10, HTSUS.

Accordingly, it is our conclusion that the operations carried out by Medline in Mexico on the imported components do not result in a substantial transformation of the items into a product of Mexico. Therefore, the origin of each item in the set will be where it was originally manufactured. Considering the sample of the latex Foley catheter tray, the specimen container, catheter foley silver, gloves, and drain bags will remain of Chinese origin. Therefore, the finished latex Foley catheter trays will be considered a product of China and U.S.A. for purposes of U.S. Government procurement. The other five tray models will follow a similar result, but as indicated only the origin of the particular catheter was provided (India or Canada for the Silvertouch model) and the origin of the accessories was not submitted.

HOLDING:

On the basis of the information provided, we find that the operations in Mexico do not constitute a substantial transformation of the components in Medline’s latex Foley catheter system management trays. Therefore, the country of origin of Medline’s Foley catheter system management trays is China and the U.S. where the items were originally manufactured for purposes of U.S. Government procurement. The other five tray

models will follow a similar result, and their country of origin will be where the items of those models were originally manufactured (India, Canada, or the U.S. as the case may be), but specific origin details were not provided for our consideration.

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. Any party-at-interest may, within 30 days after 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. 2014-15978 Filed 07/08/2014 at 8:45 am; Publication Date: 07/09/2014]