19 CFR PART 177

MODIFICATION OF TWO RULING LETTERS AND REVOCATION OF TREATMENT RELATING TO COUNTRY OF ORIGIN MARKING OF CERTAIN MIC PERCUTANEOUS PLACEMENT AND MEDICAL KITS

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

ACTION: Notice of modification of two ruling letters, and of revocation of treatment relating to the country of origin marking of certain MIC Percutaneous Placement and Medical Kits.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. § 1625(c)), as amended by section 623 of title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) is modifying two ruling letters concerning the country of origin marking of certain MIC Percutaneous Placement and Medical Kits. Similarly, CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Notice of the proposed action was published in the *Customs Bulletin*, Vol. 55, No. 40, on October 13, 2021. Two comments were received in response to that notice.

EFFECTIVE DATE: This action is effective for merchandise entered or withdrawn from warehouse for consumption on or after March 20, 2022.

FOR FURTHER INFORMATION CONTACT: Tatiana Salnik Matherne, Food, Textiles, and Marking Branch, Regulations and Rulings, Office of Trade, at (202) 325–0351.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Current customs law includes two key concepts: informed compliance and shared responsibility. Accordingly, the law imposes an obligation on CBP to provide the public with information concerning the trade community's responsibilities and rights under the customs and related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other

information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met.

Pursuant to 19 U.S.C. § 1625(c)(1), a notice was published in the *Customs Bulletin*, Vol. 55, No. 40, on October 13, 2021, proposing to modify two ruling letters pertaining to the country of origin marking of certain MIC Percutaneous Placement and Medical Kits. Any party who has received an interpretive ruling or decision (i.e., a ruling letter, internal advice memorandum or decision, or protest review decision) on the merchandise subject to this notice should have advised CBP during the comment period.

Similarly, pursuant to 19 U.S.C. § 1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Any person involved in substantially identical transactions should have advised CBP during the comment period. An importer's failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of this notice.

In HQ H016800, dated December 10, 2007, and HQ H190655, dated July 14, 2014, CBP determined that the outer containers of the MIC Percutaneous Placement and Medical Kits must be marked with a list of countries of origin of all components contained within those containers, without reference to the country of origin of each individual component. CBP has reviewed HQ H016800 and HQ H190655 and has determined the ruling letters to be in error. It is now CBP's position that the MIC Percutaneous Placement and Medical Kits must be marked to specify the country of origin of each component.

In accordance with 19 U.S.C. § 1625(c), this ruling will become effective 60 days after publication in the *Customs Bulletin*.

Dated:

For

CRAIG T. CLARK,
Director
Commercial and Trade Facilitation Division

Attachment

HQ H265715
January 5, 2022
OT:RR:CTF:FTM H265715 TSM
CATEGORY: Marking

DONALD S. STEIN, ESQ.
GREENBERG TRAURIG, LLP
800 CONNECTICUT AVENUE N.W.
SUITE 500
WASHINGTON, DC 20006

RE: Modification of HQ H016800 and HQ H190655; Country of origin marking of a certain MIC Percutaneous Placement Kit and Medical Kits.

DEAR MR. STEIN:

This is in reference to Headquarters Ruling Letter ("HQ") H016800, issued to your client, Avent Inc., on December 10, 2007, concerning the country of origin marking of a certain MIC Percutaneous Placement Kit ("PKK.") In that ruling, U.S. Customs and Border Protection ("CBP") determined that all components of the PKK kit and their country of origin need not be listed on the PKK kit packaging. Rather, the PKK kit packaging may be marked "Product of USA, Ireland and Mexico" or other words of similar meaning.[1] This is also in reference to HQ H190655, dated July 14, 2014, concerning the country of origin marking of certain medical kits. In that ruling, CBP determined that the containers of the imported medical kits must be marked with an accurate list of countries of origin of all the articles.[2] Upon additional review, we have found these determinations to be incorrect. For the reasons set forth below we hereby modify HQ H016800 and HQ H190655.

Pursuant to section 625(c)(1), Tariff Act of 1930 (19 U.S.C. 1625 (c)(1)), as amended by section 623 of Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), a notice was published in the *Customs Bulletin*, Volume 55, No. 40, on October 13, 2021, proposing to modify HQ H016800 and HQ H190655, and to revoke any treatment accorded to substantially identical transactions. Two comments generally supporting the proposed action were received on or before November 12, 2021.

FACTS:

HQ H016800, describes the subject merchandise as follows:

> The merchandise at issue is identified as the "MIC Percutaneous Placement Kit." The PPK is a medical device to initially place balloon-retained enteral feeding catheters for gastrostomy feeding. The PPK will be marketed to and used in hospitals and clinics by healthcare professionals. The PPK consists of a stoma measuring device, two syringes, 24fr dilator, a gastroplexy assembly (package containing four devices), scalpel, introducer needle, hemostat, guidewire and catheter. The stoma measuring

[1] HQ H016800 also determined the country of origin of the MIC Percutaneous Placement Kit, which is not at issue here.

[2] HQ H190655 also determined the country of origin of the medical kit and the sufficiency of marking of the outer container in lieu of marking the individual articles contained within the container. Those issues are not addressed here.

> device, 24fr dilator and catheter are from Mexico. The guidewire is from Ireland. The hemostat is from Pakistan. The syringes, gatroplexy assembly, scalpel and introducer needle are from the United States. The PPK is assembled in Mexico. The individual components of the PPK are not marked. The kit will be placed in a sealed package and sterilized. The sealed kit is then placed in individual shipping boxes.

In HQ H016800, CBP found that all components of the PPK and their country of origin need not be listed on the packaging. Rather, the packaging may be marked "Product of USA, Ireland and Mexico," "Components (or parts) produced in U.S., Ireland and Mexico" or other words of similar meaning.

HQ H190655, describes the subject merchandise as follows:

> The instant merchandise consists of various medical kits, imported into the U.S. from Mexico. The kits contain numerous components, which are organized and packaged into sub-kits. The components include items such as needles, scissors, towels, catheters, sponges, scalpels, plastic bowls, forceps, gauzes, etc. The sub-kits group various components together into a single container—for example, a box with scissors of different sizes or a sealed bag with a catheter, needles, and blades. The components are sourced from various countries, including the U.S., Canada, Mexico, China, the Dominican Republic, South Korea, Thailand and Vietnam, are assembled into sub-kits by outside suppliers, and are packaged into a single container—the final medical kit—in Mexico. The components in the sub-kits may have different countries of origin. Upon importation into the U.S., some kits are sold directly to hospitals, and some are repacked, with additional components inserted into the finished kit.
>
> The imported kits are marked on the outside container with the names of countries from which the subject merchandise may originate, for example "Products of the U.S., Mexico, China, Taiwan." The individual components are not marked.

In HQ H190655, CBP found that the outer containers of the imported medical kits must be marked with an accurate list of the countries of origin of all the articles.

ISSUE:

Whether the containers for the PKK and medical kits at issue are marked in accordance with the requirements of Treasury Decision ("T.D.") 91–7.

LAW AND ANALYSIS:

The marking statute, section 304 of the Tariff Act of 1930, as amended (19 U.S.C. § 1304) provides that, unless excepted, every article of foreign origin imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit, in such a manner as to indicate to the ultimate purchaser in the United States the English name of the country of origin of the article. Congressional intent in enacting 19 U.S.C. § 1304 was "that the ultimate purchaser should be able to know by an inspection of the marking on the imported goods the country of which the goods is the product. The evident

purpose is to mark the goods so that at the time of purchase the ultimate purchaser may, by knowing where the goods were produced, be able to buy or refuse to buy them, if such marking should influence his will." *United States v. Friedlaender & Co. Inc.*, 27 C.C.P.A. 297, 302, C.A.D. 104 (1940).

The country of origin marking requirements and the exceptions of 19 U.S.C. § 1304 are set forth in Part 134, Customs Regulations (19 C.F.R. Part 134), which implements the country of origin marking requirements and exceptions of 19. U.S.C. § 1304. Section 134.41(b), Customs Regulations (19 C.F.R. § 134.41(b)), mandates that the ultimate purchaser in the United States must be able to find the marking easily and read it without strain. 19 C.F.R. § 134.1(d), defines the ultimate purchaser as generally the last person in the United States who will receive the article in the form in which it was imported. 19 C.F.R. § 134.32(d) provides that articles for which the marking of the containers will reasonably indicate the origin of the articles are excepted from marking requirements.

The principles governing the country of origin marking of sets, mixtures, and composite goods, were addressed by CBP in Treasury Decision ("T.D.") 91–7, 25 Cust. B. & Dec. 7 (January 8, 1991). In that decision, CBP determined in relevant part that for purposes of 19 U.S.C. § 1304, the relevant inquiry is whether the materials or components have been substantially transformed as a result of their inclusion in a set, mixture, or composite good. If the materials or components have not been substantially transformed, each component must be individually marked to indicate its own country of origin.

In HQ H016800 and HQ H190655, CBP determined that the components of the PKK and medical kits, such as stoma measuring devices, syringes, dilators, gastroplexy assemblies, scalpels, needles, hemostats, guidewires, catheters, scissors, towels, sponges, plastic bowls, forceps, gauzes, etc., retained their different countries of origin. CBP further determined that the outer containers of the imported kits must be marked with an accurate list of the countries of origin of all the articles, for example "Product of USA, Ireland and Mexico," "Products of the U.S., Mexico, China, Taiwan," or other words of similar meaning.

Upon review, we find that marking of the outer containers with a list of countries of origin of all articles contained within those containers, without reference to the country of origin of each individual article, is not consistent with T.D. 91–7. As discussed above, T.D. 91–7 requires each item, if not substantially transformed as a result of its inclusion in a set, to be individually marked to indicate its own country of origin. In HQ H016800 and HQ H190655, CBP determined that the components of the PKK and medical kits retained their individual countries of origin. Accordingly, consistent with the requirements of T.D. 91–7, the PKK and medical kits must be marked to specify the country of origin of each component, for example "Catheters made in Mexico, Hemostats made in Pakistan, etc.," or its equivalent. *See* HQ H009368, dated September 27, 2007, and HQ 954260, dated May 4, 1994 (finding that the Bondex Surface Preparation Kit and Child's Fishing Kit must be marked with the countries of origin of the individual components). To the extent such foreign materials/components are insignificant, or would have no influence on the purchasing decision, CBP applies a "common sense" approach to determine whether marking is required. *See* HQ H050245, dated February 9, 2009.

As noted above, we received two comments generally supporting the proposed modification of HQ H016800 and HQ H190655. However, both com-

menters requested an extension beyond the 60-day period following the publication in the Customs Bulletin, as required by 19 U.S.C. § 1625(c), for this ruling to becomes effective. The commenters argued that additional time would be necessary to comply with the T.D. 91–7 requirement that the PKK and medical kits must be marked to specify the country of origin of each component. In addition, one of the commenters stated that CBP's proposed decision provided little guidance regarding the formatting that CBP will require when reviewing a country of origin marking dealing with dozens to potentially over one hundred individual components. The commenter requested additional guidance as to the range of marking styles that will be deemed acceptable for country of origin marking purposes and provided certain examples of potentially accepted markings.

With regard to the request for an extension beyond the 60-day period following the publication in the Customs Bulletin for this ruling to become effective, we have no statutory authority to delay the effective date of the ruling. Accordingly, this ruling will become effective 60 days after its publication in the Customs Bulletin, in accordance with 19 U.S.C. § 1625 (c). With regard to the request for additional guidance concerning specific variations and acceptable marking styles for a country of origin marking addressing medical kits with dozens of individual components, we note that a separate request for a ruling concerning country of origin marking of medical kits containing numerous components may be filed in accordance with the requirements of 19 C.F.R § 177. However, as an example of acceptable marking, we note that the following country of origin marking of the Open Heart CDS-4 procedure kit, which contains around 70 items (it is one of the products in HQ H190655), as proposed by one commenter, is in compliance with T.D. 91–7: "Gauze, plastic bags, other packaging, tape, trays, cups, lids, pitcher, basins, bowls, other containers, stockinet, light handle cover, mayo stand, needle counter, suture boot, stop flag, gowns, mop head, certain drapes, certain table covers, OR towels laparotomy sponges, bulb syringes, Yankauer bulb tips, suction tubing, anesthesia mask, cautery pen, certain surgical blades, and decanter bag made in China; tubing made in the Dominican Republic; electrodes made in Korea; sutures, pouch, breathing bag, Foly tray, anesthesia circuit, oxygen sensor, ligature clip applier, ligature clips, and skin stapler made in Mexico; CSR wrap gowns, table cover, protective sheet, certain drapes, surgical blade made in Thailand."

HOLDING:

In accordance with T.D. 91–7, the PKK and medical kits at issue in HQ H016800 and HQ H190655, must be marked with the country of origin of each component contained within those kits.

EFFECT ON OTHER RULINGS:

HQ H016800, dated December 10, 2007, is hereby MODIFIED with regard to the country of origin marking of the MIC Percutaneous Placement Kit.

HQ H190655, dated July 16, 2014, is hereby MODIFIED with regard to the country of origin marking of the medical kits.

In accordance with 19 U.S.C. § 1625(c), this ruling will become effective 60 days after its publication in the Customs Bulletin.

Sincerely,
For

CRAIG T. CLARK,
Director
Commercial and Trade Facilitation Division

PROPOSED REVOCATION OF TWO RULING LETTERS, PROPOSED MODIFICATION OF ONE RULING LETTER, AND PROPOSED REVOCATION OF TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF BANDAGE SCISSORS

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

ACTION: Notice of proposed revocation of two ruling letters, proposed modification of one ruling letter, and proposed revocation of treatment relating to the tariff classification of bandage scissors.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. § 1625(c)), as amended by section 623 of title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) intends to revoke two ruling letters and modify one ruling letter concerning tariff classification of bandage scissors under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP intends to revoke any treatment previously accorded by CBP to substantially identical transactions. Comments on the correctness of the proposed actions are invited.

DATE: Comments must be received on or before February 18, 2022.

ADDRESS: Written comments are to be addressed to U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Attention: Erin Frey, Commercial and Trade Facilitation Division, 90 K St. NE, 10th Floor, Washington, DC 20229–1177. Due to the COVID-19 pandemic, CBP is also allowing commenters to submit electronic comments to the following email address: 1625Comments@cbp.dhs.gov. All comments should reference the title of the proposed notice at issue and the *Customs Bulletin* volume, number and date of publication. Due to the relevant COVID-19-related restrictions, CBP has limited its on-site public