



DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Philips North America LLC

Ultrasound System 5100 POC Series

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 Philips North America LLC Ultrasound System 5100 POC Series. Based upon the facts presented, CBP has concluded that the last substantial transformation of the Philips North America LLC Ultrasound System 5100 POC Series occurs in the United States.

DATES: The final determination was issued on July 10, 2026. 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 FROM PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Reema Bogin, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325-7703.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on July 10, 2026, CBP issued a final determination concerning the country of origin of the Philips North America LLC Ultrasound System 5100 POC Series for purposes of Title III of the Trade Agreements Act of 1979. This final determination, Headquarters Ruling Letter (HQ) H346632, was issued at the request of Philips North America 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 the last substantial transformation of the Philips North America LLC Ultrasound System 5100 POC Series occurs in the United States.

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.



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

HQ H346632

July 10, 2026

OT:RR:CTF:VS H346632 RRB

CATEGORY: Origin

Kevin J. Maynard
Wiley Rein LLP
2050 M St NW
Washington, DC 20036

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Philips North America LLC; Country of Origin of Ultrasound System 5100 POC Series; Substantial Transformation

Dear Mr. Maynard:

This is in response to your request, dated April 3, 2025, on behalf of your client, Philips North America LLC ("Philips"), for a final determination concerning the country of origin of its Ultrasound System 5100 POC Series ("Philips Ultrasound System"), 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 C.F.R. § 177.21 *et seq.*). Philips is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and § 177.23(a) and is therefore entitled to request this final determination.

FACTS:

The merchandise at issue is the Philips Ultrasound System, which is used to perform diagnostic ultrasound imaging by transmitting and processing sound waves to create a visual representation of a patient's internal organs and tissues. It consists of a number of components and major subassemblies from various countries, including the United States, all of which are assembled together and programmed with proprietary system software at Philips' facility in Bothell, Washington.

You state that each Philips Ultrasound System consists of more than 200 individual subcomponent parts (including screws and fasteners) that are from a variety of different countries. You further explain that according to the costed bill of materials submitted with your request, approximately 53% to 56% of the material cost of the Philips Ultrasound System are costs of subcomponents that are manufactured in the United States or a TAA-designated country, including critical components such as the

display monitor and the control panel.¹ The remaining 44% to 47% of the material cost of the Philips Ultrasound System represents subcomponents from non-TAA-designated countries. Non-material costs, such as assembly, are discussed below.

You state that the Philips Ultrasound System can be grouped together into the following major subassemblies: (1) an E-box, which generates electrical signals that are transmitted to the transducer to generate soundwaves for generating patient images, and then receives signals back from the transducer that are turned into diagnostic images using Philips' proprietary software; (2) a cart subassembly, which provides the physical structure that houses all of the hardware, power supply, and electronics that comprise the finished system, allows medical professionals to transport and position the system for use, and organizes and stores cables and other accessories; (3) a transducer, which receives signals from the E-box and generates a high-pressured wave (*i.e.*, soundwave) that is propagated toward the patient tissue medium (e.g., organ, bone) to produce a diagnostic image, and also receives echoed soundwaves that are reflected from the tissue medium while transmitting that information back to the E-box for processing into an image; (4) a display monitor, which receives signals from the E-box and displays the images for user interpretation; (5) a control panel, which allows the user to turn the system on and off, as well as a touch pad and knobs for more tactile response for viewing and modifying the imaging parameters during clinical exams; and (6) proprietary system software, which controls and unifies all of the discrete functions of the finished system, including generating and processing ultrasound waves and converting into diagnostic images.

You explain that the assembly of the Philips Ultrasound System occurs in two phases. In the first phase, which takes places in Mexico, a third-party manufacturer assembles various subcomponents together to produce the E-box and cart subassemblies. In the second phase, which takes place in the United States, the E-box and cart subassemblies are assembled with the transducer and control panel (both of which are assembled in the United States) and the display monitor (sourced from a TAA country) into the finished product, which is programmed with Philips' proprietary software.

Assembly Process in Mexico

E-Box and Cart Subassemblies

As stated above, a third-party manufacturer in Mexico assembles and integrates the E-box and cart subassemblies. During the first step, which takes approximately 35 minutes to complete, more than 146 individual components, including the PC module, printed circuit board assemblies ("PCBAs"), and various hardware components, are assembled together to produce the E-box. During the second step, which also takes approximately 35 minutes to complete, 35 different hardware components, including screws, clamps, and brackets, are assembled together to produce the cart subassembly. During the third step, which also takes approximately 35 minutes to complete, the E-box and cart are assembled and wired together. Once this is completed, a test version of Philips' proprietary software, which was compiled into object code in the United States, is loaded onto the subassemblies. This test version of the software is only valid for a set duration to allow for testing, after which it will no

¹This exhibit consists of an Excel spreadsheet with separate tabs for the costed bill of materials for the "Standard" and "Pro" transducer configurations of the subject Philips Ultrasound System.

longer launch to the ultrasound application. The hard drives are re-formatted during the next phase.

You state that in total, the assembly operations in Mexico involve approximately 200 components and will take approximately 450 minutes to complete, consisting of 105 minutes of assembly, 100 minutes for loading the test version software, 110 minutes for testing, and 135 minutes for material handling and packaging. You further state that the E-box and cart subassemblies, which have been assembled and wired together, are unable to function as an ultrasound system prior to the final assembly and programming operations that will be performed in the United States.

Assembly Process in the United States

Transducer Subassembly

Assembly operations in the United States are performed at two separate Philips facilities in Reedsville, Pennsylvania, and Bothell, Washington. At the Pennsylvania facility, the transducer subassembly is assembled from various components, including a sensor from a non-TAA-designated country and a cable assembly from the United States. This is followed by various testing operations on each transducer subassembly. In total, the transducer assembly and testing operations performed at the Pennsylvania facility take approximately 90 minutes to complete (approximately 20 minutes of assembly plus approximately 70 minutes of testing).² You provided our office with a confidential and proprietary list of assembly steps that occur in the United States.

Final Assembly

The next stage of assembly operations in the United States moves to Philips' facility in Washington. Assembly operations here include final assembly, integration, and testing of the finished Philips Ultrasound System. Here, the E-box and cart are assembled together with the transducer, the display monitor (sourced from a TAA-designated country), the control panel (sourced from a third-party manufacturer in the United States), and other minor components and accessories (e.g., storage bins, gel and cable holder, probe holder, and printer subassemblies) to produce the finished ultrasound system. As part of the final assembly operations, a final, updated version of the system software, which was developed in both the United States and a non-TAA-designated country and compiled into object code in the United States, is programmed onto the E-box. In total, the assembly operations performed at the Washington facility involve 26 components and take approximately 320 minutes to complete (approximately 40 minutes of assembly, 100 minutes of programming time, 140 minutes for testing, and 40 minutes for order configuration, such as picking accessories).

In combination, the two stages of the assembly process at Philips' facilities in the United States involve approximately 32 components and take approximately 410 minutes to complete (60 minutes of assembly, 100 minutes of programming the system with software, 210 minutes for testing, and 40 minutes for order configuration). You state that only after these final assembly and programming operations have been

² You state that there are two configurations of the Philips Ultrasound System. One configuration uses a "Standard" transducer, while the other configuration uses a "Pro" transducer. You confirm that the transducer subassembly used in both of these configurations is assembled and tested in the United States as part of the final assembly process.

completed in the United States is the Philips Ultrasound System able to function as an ultrasound system.

Upon request from our office, you also provided color exploded-view diagrams of each subcomponent and manufacturing process flow charts for the production of the E-box, cart subassembly, and final assembly operations. In response to additional inquiry from our office, you also provided an updated costed bill of materials for the Philips Ultrasound System and for the transducer subassembly.

ISSUE:

What is the country of origin of the Philips Ultrasound System for purposes of U.S. Government procurement?

LAW AND 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 C.F.R. §§ 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 stems from 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 C.F.R. 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 25.403(c)(1).

The FAR, 48 C.F.R. § 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.

The FAR, 48 C.F.R. § 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.

Once again, we note that the Philips Ultrasound Systems are assembled in Mexico and the United States, with components sourced from both TAA-designated countries, as well as non-TAA-designated countries. Mexico is a TAA-designated country.

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 *Data General v. United States*, 4 C.I.T. 182 (1982), the court determined that the programming of a foreign PROM (“Programmable Read-Only Memory” chip) in the United States substantially transformed the PROM into a U.S. article. In the United States, the programming bestowed upon each integrated circuit its electronic function, that is, its “memory,” which could be retrieved. The court concluded that the programming altered the character of the PROM and that altering the non-functioning circuitry comprising the PROM through technological expertise in order to produce a functioning read only memory device, possessing a desired distinctive circuit pattern, was no less a “substantial transformation” than the manual interconnection of transistors, resistors and diodes upon a circuit board creating a similar pattern. The programming established the “essence” of the PROM, its pattern of interconnections, or stored memory.

In Headquarters Ruling Letter (“HQ”) H219597, dated April 3, 2013, two ultrasound systems, identified as the S2000 and Antares ultrasound systems, were engineered, designed and subject to final assembly in the United States from U.S. and foreign components. CBP noted that substantial manufacturing operations were performed in China, the United States, Korea, and Italy. The electronics module, which was partially assembled in China, was imported into the United States, where it was assembled with other core components, including Korean-origin transducers that sent and received acoustic signals, an Italian-origin monitor that displayed images, and a

U.S.-origin control panel that served as the user interface. The completely assembled ultrasound systems were then uploaded with U.S. designed, developed, and written operating system software and application software. The information provided indicated that the software was necessary for the ultrasound systems to perform their intended function of providing diagnostic information (an observable image with related data). It took approximately 23-24 hours to produce the finished S2000 ultrasound system of which 13-14 hours took place in the United States. Approximately 24-25 hours of time were expended to produce the finished Antares ultrasound system of which 14-15 hours took place in the United States. In addition, the assembly, integration, and testing in the United States were conducted by specialized technicians. All of the research and development, product engineering, and design investment occurred in the United States. Based on the totality of the circumstances, CBP found that the last substantial transformation occurred in the United States, the location where the final assembly and installation of the operating system software and application software occurred. Prior to the assembly and programming in the United States, the products were unable to carry out the functions of the ultrasound systems. However, the assembly and programming in the United States created a new product that was capable of providing diagnostic information. Consequently, CBP found that the country of origin of the ultrasound systems was the United States.

HQ H203555, dated April 23, 2012, concerned the country of origin of certain oscilloscopes. CBP considered five manufacturing scenarios. In the various scenarios, the motherboard and the power controller of either Malaysian or Singaporean origin were assembled in Singapore with subassemblies of Singaporean origin into oscilloscopes. CBP found that under the various scenarios, there were three countries under consideration where programming and/or assembly operations took place, the last of which was Singapore. CBP noted that no one country's operations dominated the manufacturing operations of the oscilloscopes. As a result, while the boards assembled in Malaysia were important to the function of the oscilloscopes, and the U.S. firmware and software were used to program the oscilloscopes in Singapore, the final programming and assembly of the oscilloscopes was in Singapore; hence, Singapore imparted the last substantial transformation, and the country of origin of the oscilloscopes was Singapore.

In the instant matter, the ultrasound system is comprised of various components and subassemblies from several countries, including the United States, Mexico, and other TAA-designated and non-TAA-designated countries. For example, the E-box and cart subassemblies are assembled in Mexico. The display monitor is sourced from a TAA-designated country while the control panel is manufactured in the United States. Also in the United States, the components of the transducer subassembly are assembled together in a relatively minor operation. While the essential function of the transducer subassembly is imparted by the sensor sourced from a non-TAA-designated country, the transducer subassembly is further integrated and assembled together in the United States with various subassemblies sourced either from TAA-designated countries or manufactured in the United States, including the E-box and cart subassemblies, the display monitor, control panel, and other components and accessories to produce the ultrasound system in the United States. The completely assembled ultrasound systems are then programmed with a final, updated version of the proprietary system software in the United States. As previously noted, the processing in Mexico takes approximately 450 minutes while the processing in the

United States takes approximately 410 minutes. We further note that along with a combined 860 minutes of processing that occurs in the United States or Mexico (a TAA-designated country), approximately 53% to 56% of the material cost of the subject merchandise are costs of subcomponents that are manufactured in the United States or a TAA-designated country. You state that prior to the final assembly, programming, and testing operations performed in the United States, none of the subassemblies is able to carry out the functions of an ultrasound system. Thus, the subject ultrasound system is capable of producing diagnostic images only after these subassemblies are assembled together and programmed with software in the United States.

As in HQ H219597, the loading of the proprietary software in the United States, which was partially developed in the United States where the object code was also compiled, is necessary to “translate” the signals from the transducer into images to be displayed on the monitor. In addition, both in HQ H219597 and in the instant manufacturing scenario, the core subassemblies are manufactured or sourced from various countries but are unable to carry out the functions of an ultrasound system until they are assembled together and programmed in the United States. Unlike in HQ H219597, a greater and more equivalent amount of manufacturing operations occurs across two countries, the United States and Mexico, compared to manufacturing operations occurring in non-TAA-designated countries. Nevertheless, the ultrasound system is not functional until final assembly and programming in the United States that occurs after manufacturing operations in Mexico are complete. Therefore, based on the totality of the circumstances, we find that the last substantial transformation occurs in the United States, the location where the final assembly and proprietary software programming occur. Prior to these operations in the United States, the products are unable to carry out the functions of ultrasound systems. Thus, the assembly and programming in the United States create a new product that is capable of providing diagnostic information. Consequently, we find that the last substantial transformation occurs in the United States, and therefore, the Philips Ultrasound System is not a product of a foreign country or instrumentality designated pursuant to 25 U.S.C. § 2511(b). As to whether the Philips Ultrasound System produced in the United States qualifies as a “U.S.-made end product,” you may wish to consult the relevant government procuring agency and review *Acetris Health, LLC v. United States*, 949 F.3d 719 (Fed. Cir. 2020).

HOLDING:

Based on the facts and analysis set forth above, the country of origin of the Philips Ultrasound System will be considered the United States 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 U.S. Court of International Trade.

Sincerely,

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

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