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BUREAU OF CUSTOMS

MAKABAGONG ADUANA, MATATAG NA EKONOMIYA

PROFESSIONALISM INTEGRITY ACCOUNTABILITY

19 October 2021

CUSTOMS MEMORANDUM CIRCULAR
NO. 237 - 2021

To: All Deputy Commissioners
The Assistant Commissioner
All Directors and Division Chiefs
All District/ Port Collectors
All Others Concerned

SUBJECT: TARIFF CLASSIFICATION DISPUTE RULING

Pursuant to Commission Order No. 2018-1 (Rules of Procedure on Disputes involving Tariff Classification), attached is the copy of Tariff Classification Circular Dispute Ruling (TCC/DR) No. 21-004 issued on 12 October 2021.

For your information and guidance.

For record purposes, please confirm the dissemination of this circular throughout your offices within fifteen (15) days from receipt thereof.

REY LEONARDO B. GUERRERO
Commissioner

BOC-09-25193

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CMC NO. 237 - 2021

REPUBLIC OF THE PHILIPPINES
TARIFF COMMISSION

BUREAU OF CUSTOMS
MESSAGE CENTER
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BY: RONALD JAMES T. RUIZO TIME: 1000

RE: REQUEST FOR TARIFF CLASSIFICATION DISPUTE RULING ON "INSTANT-VIEW® PREGNANCY URINE CASSETTE TEST" CONSIGNED TO MERCK SHARP AND DOHME (I.A.) LLC

(Import Entry/Customs Reference No. C-78743, NAIA)

TCC (DR) NO. 21-004

BOC-09-25193

Issued on: 12 October 2021

TARIFF CLASSIFICATION DISPUTE RULING

Before this Commission is a request for tariff classification dispute ruling (TCDR), pursuant to Paragraph 2 of Section 1100 of Republic Act No. 10863, otherwise known as the Customs Modernization and Tariff Act (CMTA), on the shipment of INSTANT-VIEW® PREGNANCY URINE CASSETTE TEST imported by Merck Sharp and Dohme (I.A.) LLC (Importer/Consignee) from Germany. The request of the Importer/Consignee for TCDR was accepted by this Commission on 20 August 2021.

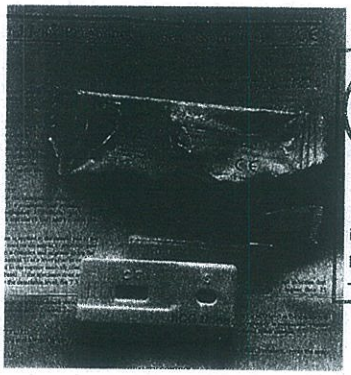
The shipment of the said article, declared under ASEAN Harmonized Tariff Nomenclature (AHTN) 2017 subheading 3002.15.00, with a Most Favoured Nation (MFN) rate of duty of 1% *ad valorem*, was processed under Import Entry/Customs Reference No. C-78743 at the Bureau of Customs (BOC), Ninoy Aquino International Airport (NAIA). The BOC contested the declared heading and reclassified subject article under AHTN 2017 subheading 3822.00.30, with an MFN rate of duty of 3% *ad valorem*.

Hence, this request for tariff classification dispute ruling.

Pursuant to Section 7.3 of Commission Order No. 2018-01, this Commission requested the concerned BOC District Collector on 27 August 2021 for comments on the request for TCDR on Instant-View® Pregnancy Urine Cassette Test. In a letter dated 09 September 2021, Atty. Halleck A. Valdez, Deputy Collector for Assessment of BOC Port of NAIA, submitted BOC's comment through a memorandum prepared by Ms. Lorraine Candelaria O. De Belen, Customs Operation Officer III of the DHL Assessment Unit, stating that the subject good was re-classified from the declared AHTN 2017 subheading 3002.15.00 (1%) to 3822.00.30 (3%). The basis for this decision as stated in the memorandum, is as follows:

"HS Code 3822.00.30 in the AHTN 2017 composed of sterilization indicator strips and tapes. And as per actual physical examination, the items were found to be Pregnancy Test Kit."

BOC provided the attached pictures from actual physical examination, for reference.



REPUBLIC OF THE PHILIPPINES
BUREAU OF CUSTOMS
OFFICE OF THE DEPUTY COMMISSIONER
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BY:
DATE: 10 Oct 21
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In the evaluation of disputes on tariff classification, Section 8 of Commission Order No. 2018-01 provides that this Commission, if it deems necessary, shall conduct a hearing to clarify the facts necessary to resolve the pending dispute in the tariff classification. In the present case, however, this Commission found that the submissions of the Importer/Consignee are sufficient to make a correct determination on the tariff classification of the subject article. A hearing, therefore, is no longer necessary.

After due examination of the submitted product insert and photograph of the actual product, it is established that subject article is a qualitative immunoassay used by healthcare professionals for the early detection of pregnancy. It is packed in a foil pouch containing one cassette test device, a dropper pipette, package insert, and desiccant. It is an in-vitro diagnostic test kit based on the detection of the human chorionic gonadotropin (hCG), a hormone produced by the placenta, in human urine. In normal subjects, hCG in urine provides an early indication of pregnancy.

Subject article uses a monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay. The test strip in the device includes: 1) a conjugate pad containing mouse monoclonal anti-hCG antibody conjugated to colloidal gold, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). A positive result is denoted by the appearance of both C line and T line in the viewing window, indicating that hCG is detected in the specimen at a level close to or greater than 25 mIU/ml while a negative test result is denoted by the appearance of the C line only, indicating that the hCG level in the specimen is not detectable.

Heading 30.02 of the AHTN 2017 covers, among others, antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes. The Harmonized System (HS) Explanatory Notes (EN) to this heading state that:

"The heading covers, among others, immunological products, whether or not modified or obtained by means of biotechnological processes.

Products used for diagnostic or therapeutic purposes and for immunological tests are to be regarded as falling within this product group. They can be defined as, among others, monoclonal antibodies (MAB). These are specific immunoglobulins from selected and cloned hybridoma cells cultured in a culture medium or ascites."

On the other hand, heading 38.22 of the AHTN 2017 (which the BOC considered) covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 30.02 or 30.06. The HS EN to this heading state that:

"Reagents of this heading are either on a backing or in the form of preparations and thus comprise more than a single constituent. For example, they may consist of admixtures of two or more reagents or of single reagents dissolved in solvents other than water. They may also be in the form of paper, plastics or other materials (used as backings or support), impregnated or coated with one or more diagnostic or laboratory reagents, such as litmus, pH or pole-finding papers or pre-coated immuno-assay plates. Reagents of this heading may also be put up in the form of kits, consisting of several components, even if one or more components are separate chemically defined compounds of Chapter 28 or Chapter 29, synthetic colouring matter of heading 32.04 or any other substance which, when presented separately, would be classifiable under another heading. Examples of such kits are those for testing glucose in blood, ketones in urine, etc., and those based on enzymes. However, diagnostic kits having the essential character of products of ***heading*** *30.02 or 30.06 (e.g., those based on monoclonal or polyclonal antibodies) are* ***excluded****."*

Furthermore, the Supplementary Explanatory Notes (SEN) to AHTN 2017 subheading 3822.00.30 (*Sterilisation indicator strips and tapes*), where the BOC classified subject article, describes "sterilisation indicator strips and tapes" as follows:

"Gummed strips and tapes of paper, used with autoclave equipment, that when subjected to high temperature and pressure change in colour to indicate successful sterilisation."

Subject article, being a pregnancy urine test that uses a monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay to accurately detect hCG at the level close to or greater than 25mIU/ml, falls under heading 30.02 of the AHTN 2017.

Based on the information from the Importer/Consignee, the BOC, and the foregoing HS EN, subject article is classified under AHTN 2017 subheading 3002.15.00 by virtue of Rules 1 and 6 of the General Rules for the Interpretation (GRI) of the HS (Section 1610 of the CMTA).

CMC No. 237- 2021

WHEREFORE, premises considered, subject article is hereby classified as follows:

Product	AHTN 2017 Code	2021 MFN Rate
Instant-View® Pregnancy Urine Cassette Test	3002.15.00	1%

This is for compliance by the BOC pursuant to Section 1100 of the CMTA.

So Ordered.

FOR THE COMMISSION

Digitally signed

MARILOU P. MENDOZA
Chairperson

TCC (DR) No. 21-004 Final

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