

BUREAU OF CUSTOMS MAKABAGONG ADUANA, MATATAG NA EKONOMIYA



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14 October 2021

CUSTOMS MEMORANDUM CIRCULAR NO. 214-2021

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. 21-005 issued on 08 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.



10/8/21, 12:17 PM

Mail - BOC OFFICE OF THE COMMISSIONER - Outlook

BOC-09-25118

Re: TCC (DR) No. 21-005: Final Ruling

Tariff Commission <tc.assist@mail.tariffcommission.gov.ph>
Fri 10/8/2021 10:54 AM

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Dear Sir/Madam:

Good day!

In addition to our earlier email and to enable us to serve you better, please fill up our online feedback form: https://cutt.ly/feedbackTC

Thank you.

TARIFF COMMISSION

Records Unit

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www.tariffcommission.gov.ph

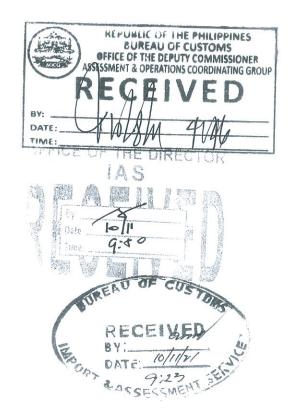
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ROMALD JAMES T. RUIZO

TIME: 320

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REPUBLIC OF THE PHILIPPINES

TARIFF COMMISSION

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

TCC (DR) NO. 21-005

(Import Entry/Customs Reference No. C-78712, NAIA)

issued on: 08 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 DIP-STRIP TEST imported by Merck Sharp and Dohme (I.A.) LLC (Importer/Consignee) from the United States of America. 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-78712 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 Dip-Strip 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.





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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 box containing 50 test strips (in foil pouch, with desiccant) and a package insert. 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 consists of a conjugate pad containing mouse monoclonal anti-hCG antibody conjugated to colloidal gold, and a nitrocellulose membrane strip 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, indicating that hCG is detected in the specimen at a level close to or greater than 25 mlU/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 Note (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 dip-strip 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).



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

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

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

So Ordered.

FOR THE COMMISSION

Thank P Thunky

MARILOU P. MENDOZA

Chairperson



TCC (DR) NO. 21-005

TCC (DR) No. 21-005 Final

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