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AOCG Memo No. 06-2023

# BUREAU OF CUSTOMS

MAKABAGONG ADUANA, MATATAG NA EKONOMIYA

PROFESSIONALISM INTEGRITY ACCOUNTABILITY

**MEMORANDUM**

**TO** : **ALL DISTRICT and SUB-PORT COLLECTORS**
**ALL CHIEFS, FORMAL ENTRY DIVISION**
**AND FORMAL ENTRY DIVISION PERSONNEL**

**FROM** : **ATTY. EDWARD JAMES A. DY BUCO**
Deputy ~~Commissioner~~, AOCG

**SUBJECT** : **TARIFF COMMISSION CIRCULARS/ADVANCE RULINGS (TCC/AR)**

**DATE** : 19 December 2022

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Pursuant to the provisions of Section 1603 (f) of the Customs Modernization and Tariff Act (Republic Act 10863) and Section 4.9 of Commission Order No. 2017-1 (Procedure on Application for an Advance Ruling on Tariff Classification related to Importation of Goods), the Tariff Commission furnished copies of the Advance Ruling (AR) on Tariff Classification with Tariff Classification Circulars (TCC/AR) issued on 02 December 2022 and the same having been reviewed and summarized as follows:

| TCC. NO. | DESCRIPTION OF ARTICLES | 2022 AHTN CODE | 2022 RATES OF DUTY |
|---|---|---|---|
| 22-513 | "BOSPHORE® C. ALBICANS DETECTION KIT V1" | 3822.19.00 | MFN – 1% Ad Valorem |
| 22-514 | "BOSPHORE® GENITAL ULCER PANEL KIT " | 3822.19.00 | MFN – 1% Ad Valorem |
| 22-515 | "BOSPHORE® HELICOBACTER PYLORI DETECTION KIT V1" | 3822.19.00 | MFN – 1% Ad Valorem |
| 22-516 | "BOSPHORE® HPV GENOTYPING HIGH RISK KIT V2" | 3822.19.00 | MFN – 1% Ad Valorem |
| **Subject to submission of their corresponding CERTIFICATES OF ORIGIN (COs).** | | | |

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| TCC. NO. | DESCRIPTION OF ARTICLES | 2022 AHTN CODE | 2022 RATES OF DUTY |
|---|---|---|---|
| 22-517 | "BOSPHORE® HPV GENOTYPING HIGH RISK KIT V1" | 3822.19.00 | MFN – 1% Ad Valorem |
| 22-518 | "BOSPHORE® STDs PANEL KIT V1" | 3822.19.00 | MFN – 1% Ad Valorem |
| 22-519 | "BOSPHORE® CANDIDA BASIC PANEL KIT V2 " | 3822.19.00 | MFN – 1% Ad Valorem |
| 22-520 | "BOSPHORE® STD URETHRITIS MINI PANEL KIT " | 3822.19.00 | MFN – 1% Ad Valorem |
| **Subject to submission of their corresponding CERTIFICATES OF ORIGIN (COs).** | | | |

**For information, guidance and strict compliance.**

***CC: COMMISSIONER OF CUSTOMS***

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REPUBLIC OF THE PHILIPPINES
TARIFF COMMISSION

TCOC Ref. No. 22-094

02 December 2022 BOC-09-36214

BUREAU OF CUSTOMS
MESSAGE CENTER
RECEIVED
DEC 05 2022
RONALD JAMES T. RUIZO
ADMINISTRATIVE SERVICES OFFICER
TIME: 943

**ACTING COMMISSIONER YOGI FILEMON I. RUIZ**
Bureau of Customs
G/F OCOM Building
16th Street, South Harbor
Gate 3 Port Area, Manila

Dear **Acting Commissioner Ruiz**:

Pursuant to the provisions of Section 1603(f) of the Customs Modernization and Tariff Act (Republic Act No. 10863) and Section 4.9 of Commission Order No. 2017-1 (Procedure on Application for an Advance Ruling on Tariff Classification Related to Importation or Exportation of Goods), this Commission is pleased to furnish your good Office with PDF copies of additional eight Advance Rulings on Tariff Classification, with TCC (AR) Nos. 22-513, 22-514, 22-515, 22-516, 22-517, 22-518, 22-519, and 22-520, issued by this Commission on 02 December 2022. These Advance Rulings have also been posted on the Commission's website *www.tariffcommission.gov.ph*.

REPUBLIC OF THE PHILIPPINES
BUREAU OF CUSTOMS
OFFICE OF THE DEPUTY COMMISSIONER
ASSESSMENT & OPERATIONS COORDINATING GROUP
RECEIVED
BY:
DATE:
TIME:

Thank you.

Very truly yours,

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

*Encl:* *As stated*

*cc:* *The Secretary*
*Department of Finance*
*Manila*

12/12
3:35

BUREAU OF CUSTOMS
RECEIVED
BY:
DATE: 12 DEC 2022
IMPORT ASSESSMENT SERVICE

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REPUBLIC OF THE PHILIPPINES

# TARIFF COMMISSION

## ADVANCE RULING ON TARIFF CLASSIFICATION

Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-515** |
| **3** | **DATE ISSUED** |
| | **02 December 2022** |

**4 DESCRIPTION OF GOOD**

**"BOSPHORE® HELICOBACTER PYLORI DETECTION KIT V1"**


Based on the user manual, safety data sheet, production workflow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection of *Helicobacter pylori* deoxyribonucleic acid (DNA) in human biological samples. Based on the Real-Time Polymerase Chain Reaction (PCR) technique, a region within the 23S ribosomal ribonucleic acid (RNA) gene is amplified and fluorescence detection is accomplished using CY5 filter. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mix | Taq DNA Polymerase, PCR buffer, dNTP mix, primers, and dual-labeled probes |
| | Internal control | Synthetic DNA molecule |
| | Positive control | *Helicobacter pylori* DNA |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 483, Montania® 484 or Montania® 4896; iCycler, iQ5, CFX-BioRad, etc. |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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| 2 | TCC (AR) NO. |
|---|---|
| | 22-515 |

## 5 REASONS FOR CLASSIFICATION

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for *in vitro* or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

In view thereof, subject article is classified under AHTN 2022 subheading 3822.19.00, with a Most Favoured Nation (MFN) rate of duty of 1% ad valorem.

This ruling shall be valid for five years from the date of issuance and shall continue to apply unless the law, facts, or circumstances supporting this ruling have changed.

FOR THE COMMISSION

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

***Note:*** *In line with the Commission's objective to provide alternative mediums/channels of communication and to further enhance the accessibility of its frontline services to its stakeholders, this Advance Ruling is being issued in digital format, without a dry seal, barcode, and hologram, and is also uploaded in the Tariff Commission website. A hard copy thereof, accompanied by said dry seal, barcode, and hologram, may be issued upon request.*

AOCG Memo No. 06-2023 p.6

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REPUBLIC OF THE PHILIPPINES

# TARIFF COMMISSION

## ADVANCE RULING ON TARIFF CLASSIFICATION

Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-516** |
| **3** | **DATE ISSUED** |
| | **02 December 2022** |

**4 DESCRIPTION OF GOOD**

**"BOSPHORE® HPV GENOTYPING HIGH RISK KIT V2"**

Based on the user manual, safety data sheet, production work flow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection of the high risk group of human papilloma virus (HPV) genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and characterization of HPV genotype 16 and 18 in human biological samples including tissue/biopsy specimen, swabs (*e.g.*, flocking swabs and liquid amies; vaginal, endocervical, and urethral swabs). Based on the Real-Time Polymerase Chain Reaction (PCR) technique, a specific HPV genotype is amplified, and fluorescence detection is accomplished using FAM, HEX, or Texas RED filter. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mix | Taq deoxyribonucleic acid (DNA) Polymerase, PCR buffer, dNTP mix, primers, dual-labeled probes |
| | Positive control | Synthetic nucleic acid sequences of HPV genotypes |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 484 or Montania® 4896; CFX96-BioRad, LightCycler 480-Roche, or QuantStudio 5 - ABI |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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| 2 | TCC (AR) NO. |
|---|---|
| | 22-516 |

**5 REASONS FOR CLASSIFICATION**

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for *in vitro* or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

In view thereof, subject article is classified under AHTN 2022 subheading 3822.19.00, with a Most Favoured Nation (MFN) rate of duty of 1% ad valorem.

This ruling shall be valid for five years from the date of issuance and shall continue to apply unless the law, facts, or circumstances supporting this ruling have changed.

FOR THE COMMISSION

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

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REPUBLIC OF THE PHILIPPINES

# TARIFF COMMISSION

## ADVANCE RULING ON TARIFF CLASSIFICATION

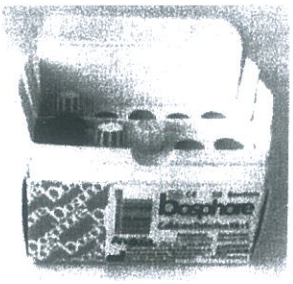
Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-513** |
| **3** | **DATE ISSUED** |
| | **02 December 2022** |

**4 DESCRIPTION OF GOOD**

**"BOSPHORE® C. ALBICANS DETECTION KIT V1"**



Based on the user manual, safety data sheet, production workflow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection of Candida albicans (C. albicans) deoxyribonucleic acid (DNA) in human biological samples such as blood, blood culture, epithelial cells, semen, urine, and prostatic secretions. Based on the Real-Time Polymerase Chain Reaction (PCR) technique, a region within the Internal Transcribed Spacer 2 (ITS2) gene is amplified and fluorescence detection is accomplished using FAM filter. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mix | Taq DNA Polymerase, PCR buffer, dNTP mix, primers, and dual-labeled probes |
| | Internal control | Synthetic DNA molecule |
| | Positive control | C. albicans DNA |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 483, Montania® 484 or Montania® 4896; iCycler, iQ5, CFX-BioRad, etc. |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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| 2 | TCC (AR) NO. |
|---|---|
| | 22-513 |

## 5 REASONS FOR CLASSIFICATION

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for *in vitro* or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

In view thereof, subject article is classified under AHTN 2022 subheading 3822.19.00, with a Most Favoured Nation (MFN) rate of duty of 1% ad valorem.

This ruling shall be valid for five years from the date of issuance and shall continue to apply unless the law, facts, or circumstances supporting this ruling have changed.

FOR THE COMMISSION

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

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REPUBLIC OF THE PHILIPPINES

# TARIFF COMMISSION

## ADVANCE RULING ON TARIFF CLASSIFICATION

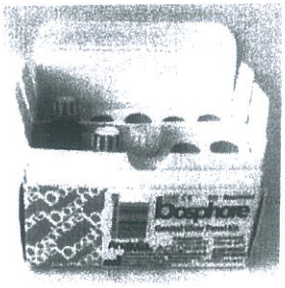
Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-514** |
| **3** | **DATE ISSUED** |
| | **02 December 2022** |

**4 DESCRIPTION OF GOOD**

**"BOSPHORE® GENITAL ULCER PANEL KIT"**




Based on the user manual, safety data sheet, production workflow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection and characterization of herpes simplex virus type 1 (HSV-1), HSV-2, and *Treponema pallidum* deoxyribonucleic acid (DNA) in human biological samples including urine, tissue/biopsy specimen, swabs (flocking swabs and liquid amies, vaginal swab, and endocervical swab, among others), and semen sample. Based on the Real-Time Polymerase Chain Reaction (PCR) technique, HSV-1, HSV-2, and *Treponema pallidum* genomes are amplified and fluorescence detection is accomplished using FAM, HEX, Texas RED, and Cy5 filters. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mix | Taq DNA Polymerase, PCR buffer, dNTP mix, primers, and dual-labeled probes |
| | Internal control | Synthetic DNA molecule |
| | Positive control | DNA of HSV-1, HSV-2, and *Treponema pallidum* |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 484 or Montania® 4896; iCycler, iQ5, CFX-BioRad, etc. |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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| 2 | TCC (AR) NO. |
|---|---|
| | 22-514 |

| 5 | REASONS FOR CLASSIFICATION |
|---|---|

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for *in vitro* or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

In view thereof, subject article is classified under AHTN 2022 subheading 3822.19.00, with a Most Favoured Nation (MFN) rate of duty of 1% ad valorem.

This ruling shall be valid for five years from the date of issuance and shall continue to apply unless the law, facts, or circumstances supporting this ruling have changed.

FOR THE COMMISSION

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

***Note:*** *In line with the Commission's objective to provide alternative mediums/channels of communication and to further enhance the accessibility of its frontline services to its stakeholders, this Advance Ruling is being issued in digital format, without a dry seal, barcode, and hologram, and is also uploaded in the Tariff Commission website. A hard copy thereof, accompanied by said dry seal, barcode, and hologram, may be issued upon request.*

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REPUBLIC OF THE PHILIPPINES

# TARIFF COMMISSION

## ADVANCE RULING ON TARIFF CLASSIFICATION

Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-519** |
| **3** | **DATE ISSUED** |
| | **02 December 2022** |

**4 DESCRIPTION OF GOOD**

**"BOSPHORE® CANDIDA BASIC PANEL KIT V2"**

Based on the user manual, safety data sheet, production workflow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection and characterization of *Candida albicans*, *Candida glabrata*, *Candida krusei*, and *Candida parapsilosis* in blood, blood culture, serum, swab, and bronchoalveolar lavage (BAL) samples. Based on the Real-Time Polymerase Chain Reaction (PCR) technique, a region within the *Candida albicans*, *Candida glabrata*, *Candida krusei*, and *Candida parapsilosis* genomes are amplified and fluorescence detection is accomplished using FAM, HEX, Texas RED, and Cy5 filters. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mixes 1 and 2 | Taq deoxyribonucleic acid (DNA) Polymerase, PCR buffers, dNTP mixes, primers, and dual-labeled probes |
| | Internal control | Synthetic DNA molecule |
| | Positive controls 1 and 2 | DNA of *Candida albicans*, *Candida glabrata*, *Candida krusei*, and *Candida parapsilosis* |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 484 or Montania® 4896; iCycler, iQ5, CFX-BioRad, etc. |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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| 2 | TCC (AR) NO. |
|---|---|
| | 22-519 |

| 5 | REASONS FOR CLASSIFICATION |
|---|---|

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

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FOR THE COMMISSION

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

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AOCG Memo No. 06 - 2023 p. 14

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REPUBLIC OF THE PHILIPPINES

# TARIFF COMMISSION

## ADVANCE RULING ON TARIFF CLASSIFICATION

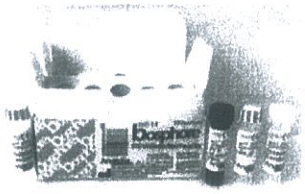
Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-520** |
| 3 | **DATE ISSUED** |
| | **02 December 2022** |

**4 DESCRIPTION OF GOOD**

**"BOSPHORE® STD URETHRITIS MINI PANEL KIT"**



Based on the user manual, safety data sheet, production workflow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection and discrimination of *Mycoplasma genitalium*, *Trichomonas vaginalis*, and *Neisseria gonorrhoeae* deoxyribonucleic acid (DNA) in human biological samples including urine, tissue/biopsy specimens, swabs (*e.g.*, flocking swabs and liquid amies, Sigma Transwab, vaginal swab, and endocervical swab), and semen samples. Based on the Real-Time Polymerase Chain Reaction (PCR) technique, a region within the *Mycoplasma genitalium*, *Trichomonas vaginalis*, and *Neisseria gonorrhoeae* DNA is amplified, and fluorescence detection is accomplished using Texas RED, HEX, and FAM filters. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mix | Taq DNA Polymerase, PCR buffer, dNTP mix, primers, and dual-labeled probes |
| | Internal control | Synthetic DNA molecule |
| | Positive control | DNA of *Mycoplasma genitalium*, *Trichomonas vaginalis*, and *Neisseria gonorrhoeae* |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 484 or Montania® 4896; iCycler, iQ5, CFX-BioRad, etc. |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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| 2 | TCC (AR) NO. |
|---|---|
| | 22-520 |

| 5 | REASONS FOR CLASSIFICATION |
|---|---|

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for *in vitro* or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

In view thereof, subject article is classified under AHTN 2022 subheading 3822.19.00, with a Most Favoured Nation (MFN) rate of duty of 1% ad valorem.

This ruling shall be valid for five years from the date of issuance and shall continue to apply unless the law, facts, or circumstances supporting this ruling have changed.

FOR THE COMMISSION

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

***Note:*** *In line with the Commission's objective to provide alternative mediums/channels of communication and to further enhance the accessibility of its frontline services to its stakeholders, this Advance Ruling is being issued in digital format, without a dry seal, barcode, and hologram, and is also uploaded in the Tariff Commission website. A hard copy thereof, accompanied by said dry seal, barcode, and hologram, may be issued upon request.*

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REPUBLIC OF THE PHILIPPINES

TARIFF COMMISSION

# ADVANCE RULING ON TARIFF CLASSIFICATION

Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-517** |
| **3** | **DATE ISSUED** |
| | **02 December 2022** |

## 4 DESCRIPTION OF GOOD

### "BOSPHORE® HPV GENOTYPING HIGH RISK KIT V1"

Based on the user manual, safety data sheet, production workflow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection and characterization of human papilloma virus (HPV) genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) in human biological samples. Based on the Real-Time Polymerase Chain Reaction (PCR) technique, fluorescence detection of a specific HPV genotype is accomplished using FAM, HEX, Texas RED, and Cy5 filters. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mixes 1, 2, 3, 4 and 5 | Taq deoxyribonucleic acid (DNA) Polymerase, PCR buffer, dNTP mix, primers, and probes |
| | Internal Control PCR | Synthetic DNA molecule (added into PCR master mix to control PCR inhibition and application errors) |
| | Internal Control EXT | Synthetic DNA molecule (added into biological sample, proteinase K and carrier RNA mixture during DNA isolation to control isolation efficiency, PCR inhibition and application errors. |
| | Positive Controls 1, 2, 3, 4 and 5 | HPV genotype-specific synthetic DNA |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 484 or Montania® 4896; iCycler, iQ5, CFX-BioRad, etc. |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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MASTER COPY

| 2 | TCC (AR) NO. |
|---|---|
| | 22-517 |

| 5 | REASONS FOR CLASSIFICATION |
|---|---|

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

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In view thereof, subject article is classified under AHTN 2022 subheading 3822.19.00, with a Most Favoured Nation (MFN) rate of duty of 1% ad valorem.

This ruling shall be valid for five years from the date of issuance and shall continue to apply unless the law, facts, or circumstances supporting this ruling have changed.

FOR THE COMMISSION

Digitally signed

Marilou P Mendoza

**MARILOU P. MENDOZA**
Chairperson

***Note:*** *In line with the Commission's objective to provide alternative mediums/channels of communication and to further enhance the accessibility of its frontline services to its stakeholders, this Advance Ruling is being issued in digital format, without a dry seal, barcode, and hologram, and is also uploaded in the Tariff Commission website. A hard copy thereof, accompanied by said dry seal, barcode, and hologram, may be issued upon request.*

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REPUBLIC OF THE PHILIPPINES

# TARIFF COMMISSION

## ADVANCE RULING ON TARIFF CLASSIFICATION

Pursuant to Section 1100 of RA 10863 (CMTA)

| 1 | AHTN 2022 CODE AND 2022 RATE/S OF IMPORT DUTY |
|---|---|
| | **AHTN 3822.19.00**<br>**MFN - 1% ad valorem** |

| 2 | TCC (AR) NO. |
|---|---|
| | **22-518** |
| 3 | **DATE ISSUED** |
| | **02 December 2022** |

**4 DESCRIPTION OF GOOD**

**"BOSPHORE® STDs PANEL KIT V1"**


Based on the user manual, safety data sheet, production workflow chart, and photograph of the product submitted, subject article is an *in vitro* diagnostic kit used for the detection and characterization of *Ureaplasma urealyticum*, *Ureaplasma parvum*, *Mycoplasma hominis*, *Neisseria gonorrhea*, *Trichomonas vaginalis*, *and Mycoplasma genitalium* in human biological samples. Based on the Real-Time Polymerase Chain Reaction (PCR) technique, a region within the *Ureaplasma urealyticum*, *Ureaplasma parvum*, *Mycoplasma hominis*, *Neisseria gonorrhea*, *Trichomonas vaginalis*, *and Mycoplasma genitalium* genomes are amplified and fluorescence detection of a specific virus is accomplished using FAM, HEX, Texas RED, and Cy5 filters. Subject article has the following specifications:

| | | |
|---|---|---|
| **Components** | **Reagent** | **Composition** |
| | Real-Time PCR master mixes 1 and 2 | Taq deoxyribonucleic acid (DNA) Polymerase, PCR buffer, dNTP mix, primers, and dual-labeled probes |
| | Internal control | Synthetic DNA molecule |
| | Positive control 1 | Synthetic DNA of *Ureaplasma urealyticum*, *Ureaplasma parvum*, and *Mycoplasma hominis* |
| | Positive control 2 | Synthetic DNA of *Neisseria gonorrhea*, *Trichomonas vaginalis*, *and Mycoplasma genitalium* |
| | Distilled water | |
| **Compatible device** | **Equipment** | **Model** |
| | Real-Time PCR Instrument/System | Montania® 484 or Montania® 4896; iCycler, iQ5, CFX-BioRad, LightCycler 480-Roche, etc. |
| **Packaging** | **Container** | **Pack size** |
| | Clear and amber plastic bottles in paper boxes | 25, 50, or 100 reactions/box |

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| 2 TCC (AR) NO. |
| --- |
| 22-518 |

| 5 | REASONS FOR CLASSIFICATION |
| --- | --- |

Heading 38.22 of the ASEAN Harmonised Tariff Nomenclature (AHTN) 2022 covers, among others, diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06. The pertinent Harmonized System (HS) Explanatory Notes (EN) 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.

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FOR THE COMMISSION

Digitally signed

**MARILOU P. MENDOZA**
Chairperson

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